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NEWS 35

Apr 21

Apr 21

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FILE COVERS 1971 TO PATENT PUBLICATION DATE: 22 Apr 2003 (20030422/PD)
FILE LAST UPDATED: 22 Apr 2003 (20030422/ED)
HIGHEST GRANTED PATENT NUMBER: US6553568
HIGHEST APPLICATION PUBLICATION NUMBER: US2003074707
CA INDEXING IS CURRENT THROUGH 22 Apr 2003 (20030422/UPCA)
ISSUE CLASS FIELDS (/INCL) CURRENT THROUGH: 22 Apr 2003 (20030422/PD)
REVISED CLASS FIELDS (/NCL) LAST RELOADED: Feb 2003
USPTO MANUAL OF CLASSIFICATIONS THESAURUS ISSUE DATE: Feb 2003

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This file contains CAS Registry Numbers for easy and accurate substance identification.

=> s skin and (vitamin A and Vitamin c and vitamind and vitamin e and vitamin .sub.3)

162870 SKIN 29053 VITAMIN 3437310 A 7731 VITAMIN A

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(VITAMIN(W)A)
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       1896340 C
          6092 VITAMIN C
                  (VITAMIN(W)C)
              8 VITAMIND
         29053 VITAMIN
       2099612 E
          9753 VITAMIN E
                  (VITAMIN(W)E)
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       3416035 3
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               AND VITAMIN .SUB.3)
=> s skin and (vitamin A and Vitamin c and vitamin d and vitamin e and vitamin B
.sub.3)
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       1737653 B
       1347524 SUB
       3416035 3
           203 VITAMIN B .SUB.3
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               AND VITAMIN B .SUB.3)
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       2605423 PD <2000
                 (PD<20000000)
L3
            17 L2 AND PD <2000
=> d 13 1-17
L3
     ANSWER 1 OF 17 USPATFULL
AN
       2000:34224 USPATFULL
ΤI
       Dietary food enhancement agent
ΙN
       Bangs, William E., Philadelphia, PA, United States
       Khoo, Chor San Heng, Mt. Laurel, NJ, United States
       Ko, Sandy, Abington, PA, United States
PA
       Campbell Soup Company, Camden, NJ, United States (U.S. corporation)
PΙ
       US 6039978
                               20000321
       WO 9639053 19961212
                                                                      <--
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19960920 (8)
ΑI
       US 1996-716421
       WO 1996-US10225
                                19960606
                                19960920 PCT 371 date
                                19960920 PCT 102(e) date
       Continuation-in-part of Ser. No. US 1995-471202, filed on 6 Jun 1995,
RLI
       now abandoned
DT
       Utility
       Granted
FS
LN.CNT 3160
INCL
       INCLM: 424/489.000
       INCLS: 426/072.000; 426/073.000; 426/074.000; 514/905.000
       NCLM: 424/489.000
NCL
       NCLS: 426/072.000; 426/073.000; 426/074.000; 514/905.000
IC
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EXF
       426/72; 426/73; 426/74; 514/904; 514/905; 424/489
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
     ANSWER 2 OF 17 USPATFULL
L3
       1999:155678 USPATFULL
AN
TΤ
       Therapeutic system for dietary health management
       Khoo, Chor San Heng, Mt. Laurel, NJ, United States
IN
       MacNair, R. David, King of Prussia, PA, United States
       Campbell Soup Company, Camden, NJ, United States (U.S. corporation)
PA
       US 5994295
PΙ
                                19991130
ΑI
       US 1997-927076
                                19970910 (8)
RLI
       Continuation of Ser. No. US 1995-466893, filed on 6 Jun 1995, now
       abandoned
DT
       Utility
FS
       Granted
LN.CNT 3239
INCL
       INCLM: 514/002.000
       INCLS: 514/023.000; 514/558.000; 514/560.000; 514/533.000
NCL
              514/002.000
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IC
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       ICM: A61K038-00
       ICS: A61K031-70; A61K031-20; A61K031-235
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CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 3 OF 17 USPATFULL
       1999:137208 USPATFULL
ΑN
ΤI
       Therapeutic system for dietary health management
IN
       Khoo, Chor San Heng, Mt. Laurel, NJ, United States
       MacNair, R. David C., King of Prussia, PA, United States
PA
       Campbell Soup Company, Camden, NJ, United States (U.S. corporation)
       US 5977059
PΙ
                                19991102
ΑI
       US 1997-926432
                                19970910 (8)
RLI
       Division of Ser. No. US 1995-466893, filed on 6 Jun 1995, now abandoned
DT
       Utility
FS
       Granted
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INCL
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NCL
              514/002.000
              514/023.000; 514/533.000; 514/558.000; 514/560.000
       NCLS:
IC
       ICM: A61K038-00
       ICS: A61K031-70; A61K031-20; A61K031-235
       514/2; 514/23; 514/558; 514/560; 514/533
EXF
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CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 4 OF 17 USPATFULL
ΑN
       1999:136663 USPATFULL
       UV protection compositions
TI
       Robinson, Larry Richard, Loveland, OH, United States
IN
       The Procter & Gamble Company, Cincinnati, OH, United States (U.S.
PA
       corporation)
                               19991102
PΙ
       US 5976513
ΑI
       US 1999-264139
                               19990305 (9)
       Continuation-in-part of Ser. No. US 1998-174225, filed on 16 Oct 1998,
RLI
       now abandoned
DT
       Utility
       Granted
FS
LN.CNT 906
       INCLM: 424/059.000
TNCL
       INCLS: 424/060.000; 424/400.000; 424/401.000
       NCLM: 424/059.000
NCL
       NCLS: 424/060.000; 424/400.000; 424/401.000
IC
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       ICS: A61K007-00
EXF
       424/59; 424/60; 424/400; 424/401
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
     ANSWER 5 OF 17 USPATFULL
L3
       1999:132881 USPATFULL
AN
       Pharmaceutical compositions and methods for improving wrinkles and other
ΤI
       skin conditions
       Murad, Howard, 4316 Marina City Dr., Marina del Rey, CA, United States
IN
       90292
PΙ
       US 5972999
                               19991026
ΑI
       US 1998-146554
                               19980903 (9)
       Continuation of Ser. No. US 1997-787358, filed on 22 Jan 1997, now
RLI
       patented, Pat. Not US 5804594
DΤ
       Utility
FS
       Granted
LN.CNT 1077
       INCLM: 514/474.000
INCL
       INCLS: 514/557.000; 514/062.000; 514/054.000; 514/801.000; 424/417.000
NCL
       NCLM: 514/474.000
       NCLS: 424/417.000; 514/054.000; 514/062.000; 514/557.000; 514/801.000
IC
       [6]
       ICM: A61K031-715
       ICS: A61K031-34; A61K031-19
       514/474; 514/557; 514/801; 514/62; 514/54; 424/417
EXF
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 6 OF 17 USPATFULL
       1999:132208 USPATFULL
ΑN
ΤI
       UV protection compositions
       Robinson, Larry Richard, Loveland, OH, United States
IN
PA
       The Procter & Gamble Company, Cincinnati, OH, United States (U.S.
       corporation)
PΙ
       US 5972316
                               19991026
                               19990305 (9)
AΤ
       US 1999-263017
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Continuation-in-part of Ser. No. US 1998-174307, filed on 16 Oct 1998,

RLT

DΤ

FS

INCL

LN.CNT 893

now abandoned

INCLM: 424/059.000

Utility

Granted

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EXF
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CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 7 OF 17 USPATFULL
       1999:128104 USPATFULL
AN
ΤI
       UV protection compositions
IN
       Robinson, Larry Richard, Loveland, OH, United States
PA
       The Procter & Gamble Company, Cincinnati, OH, United States (U.S.
       corporation)
       US 5968485
PΙ
                                19991019
                                                                      <--
AI .
       US 1999-263673
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RLI
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FS
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              424/059.000
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EXF
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     ANSWER 8 OF 17 USPATFULL
L3
AN
       1999:121419 USPATFULL
ΤI
       Pharmaceutical compositions and methods for treating acne
IN
       Murad, Howard, 4316 Marina City Dr., Marina del Rey, CA, United States
       90292
PΤ
       US 5962517
                                19991005
ΑI
       US 1998-16800
                                19980130 (9)
PRAI
       US 1997-36825P
                            19970131 (60)
DT
       Utility
FS
       Granted
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INCL
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       INCLS: 514/557.000; 514/801.000; 514/474.000; 514/062.000; 514/054.000;
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NCL
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              514/474.000
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IC
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       424/417
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 9 OF 17 USPATFULL
AN
       1998:108425 USPATFULL
TI
       Pharmaceutical compositions and methods for improving wrinkles and other
       skin conditions
ΤN
       Murad, Howard, 4316 Marina City Dr., Marina del Rey, CA, United States
       90292
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US 5804594
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PΙ
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NCL
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       ICS: A61K031-34; A61K031-19
       514/54; 514/62; 514/474; 514/557; 514/801; 424/417
EXF
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3 ANSWER 10 OF 17 USPATFULL
       1998:27757 USPATFULL
AN
ΤI
       Skin protection, fragrance enhancing and vitamin delivery
IN
       Pinzon, Carlos, Hackensack, NJ, United States
PA
       L'Oreal, S.A., Paris, France (non-U.S. corporation)
PI
       US 5728372
                                19980317
                                                                      <--
ΑI
       US 1996-643110
                                19960430 (8)
RLI
       Continuation-in-part of Ser. No. US 1996-641067, filed on 29 Apr 1996,
       now abandoned
DT
       Utility
FS
       Granted
LN.CNT 671
INCL
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       INCLS: 424/060.000; 424/400.000; 424/401.000
NCL
             424/059.000
       NCLS: 424/060.000; 424/400.000; 424/401.000
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EXF
       424/59; 424/60; 424/400; 424/401
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 11 OF 17 USPATFULL
AN
       1998:27756 USPATFULL
ΤI
       Skin protection, fragrance enhancing and vitamin delivery
       composition
IN
       Pinzon, Carlos, Hackensack, NJ, United States
       Thau, Paul, Berkley Heights, NJ, United States
PA
       L'Oreal, S.A., Paris, France (non-U.S. corporation)
PΙ
       US 5728371
                               19980317
                                                                      <--
ΑI
       US 1996-643075
                               19960430 (8)
RLI
       Continuation-in-part of Ser. No. US 1996-641066, filed on 29 Apr 1996,
       now abandoned
DT
       Utility
FS
       Granted
LN.CNT 596
INCL
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       INCLS: 424/060.000; 424/400.000; 424/401.000
NCL
       NCLM: 424/059.000
       NCLS: 424/060.000; 424/400.000; 424/401.000
IC
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EXF
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
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L3
     ANSWER 12 OF 17 USPATFULL
AN
       97:68148 USPATFULL
       Personal product compositions comprising heteroatom containing alkyl
ΤI
       aldonamide compounds
IN
       Vermeer, Robert, Nutley, NJ, United States
       Lever Brothers Company, Division of Conopco, Inc., New York, NY, United
PA
       States (U.S. corporation)
PΙ
       US 5653970
                                19970805
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       US 1994-352008
ΑI
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DT
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FS
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NCL
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EXF
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CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 13 OF 17 USPATFULL
AN
       97:53932 USPATFULL
TT
       Hair care compositions comprising heteroatom containing alkyl aldonamide
       compounds
IN
       Vermeer, Robert, Nutley, NJ, United States
       Lever Brothers Company, Division of Conopco, Inc., New York, NY, United
PA
       States (U.S. corporation)
PΙ
       US 5641480
                               19970624
                                                                     <--
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       US 1994-352309
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DT
       Utility
FS
       Granted
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INCL
       INCLM: 424/070.240
       INCLS: 424/070.100
NCL
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       NCLS: 424/070.100
IC
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       ICM: A61K007-07
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       424/70.1; 424/70.13; 424/70.17; 424/70.24
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 14 OF 17 USPATFULL
ΑN
       97:51727 USPATFULL
TI
       Method for determining diet program effectiveness
IN
       Chait, Allen, Seattle, WA, United States
       Hatton, Dan, Portland, OR, United States
       Haynes, R. Brian, Dundas, Canada
       Khoo, Chor San Heng, Mt. Laurel, NJ, United States
       Kris-Etherton, Penny, State College, PA, United States
       Macnair, R. David C., King of Prussia, PA, United States
       McCarron, David, Portland, OR, United States
       Metz, Jill, Portland, OR, United States
       Oparil, Suzanne, Birmingham, AL, United States
       Pi-Sunyer, Xavier, New York, NY, United States
       Resnick, Larry, West Bloomfield, MI, United States
       Stern, Judith S., Lafayette, CA, United States
       Ziegler, Paula J., Cherry Hill, NJ, United States
PA
       Campbell Soup Company, Camden, NJ, United States (U.S. corporation)
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                               19970617
       US 5639471
PΤ
                               19950606 (8)
       US 1995-469516
ΑI
DT
       Utility
       Granted
FS
LN.CNT 3163
INCL
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       INCLS: 424/400.000
       NCLM:
             424/439.000
NCL
       NCLS: 424/400.000
       [6]
IC
       ICM: A61K047-00
       424/439; 424/400; 424/440
EXF
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
L3
     ANSWER 15 OF 17 USPATFULL
ΑN
       95:49940 USPATFULL
       Methods of treatment and devices employing lithium salts
TI
IN
       Horrobin, David F., Haslemere, United Kingdom
       Efamol Holding PLC, Surrey, United Kingdom (non-U.S. corporation)
PΑ
                                19950606
PΙ
       US 5422115
       US 1992-963597
                                19921020 (7)
ΑI
       Division of Ser. No. US 1989-329881, filed on 28 Mar 1989, now abandoned
RLI
       which is a continuation of Ser. No. US 1988-182291, filed on 15 Apr
       1988, now abandoned
PRAI
       GB 1987-9892
                            19870427
       GB 1987-19988
                            19870825
       GB 1988-2016
                            19880129
DT
       Utility
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FS
LN.CNT 974
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INCL
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              424/436.000; 514/810.000; 514/821.000; 514/866.000; 514/886.000;
              514/825.000; 514/885.000; 514/824.000; 514/931.000; 514/934.000
NCL
       NCLM:
              424/422.000
              424/423.000; 424/436.000; 424/474.000; 424/475.000; 424/480.000;
       NCLS:
              424/482.000; 514/810.000; 514/821.000; 514/824.000; 514/825.000;
              514/866.000; 514/885.000; 514/886.000; 514/931.000; 514/934.000
IC
       [6]
       ICM: A61K009-28
       ICS: A61K031-20
       424/464; 424/465; 424/474; 424/475; 424/480; 424/482; 424/422; 514/558
EXF
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
     ANSWER 16 OF 17 USPATFULL
L3
AN
       93:84885 USPATFULL
TΙ
       Lithium salt-containing pharmaceutical compositions
IN
       Horrobin, David F., Haslemere, United Kingdom
       Scotia Holdings PLC, Surrey, United Kingdom (non-U.S. corporation)
PA
PΙ
       US 5252333
                                19931012
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ΑI
       US 1989-329881
                                19890328 (7)
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RLI
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PRAI
                            19870825
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INCL
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              514/905.000; 514/943.000
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NCLM:
              424/422.000
NCL
              424/445.000; 424/449.000; 424/463.000; 424/474.000; 424/490.000;
       NCLS:
              514/905.000; 514/943.000
IC
       [5]
       ICM: A61F013-00
       ICS: A61K009-00; A61K031-20
       424/430; 424/445; 424/449; 424/474; 514/560; 514/60; 514/558
EXF
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
     ANSWER 17 OF ,17 USPATFULL
L3
       93:31203 USPATFULL
AN
       Hypoallergenic milk products from natural and/or synthetic components
ΤI
       and process of making
TN
       Girsh, Leonard S., South Palm Beach, FL, United States
       Immuno Path Profile, Inc., Melrose Park, PA, United States (U.S.
PA
       corporation)
                               19930420
                                                                     <--
PΙ
       US 5204134
ΑI
       US 1991-754872
                               19910904 (7)
       Continuation-in-part of Ser. No. US 1990-562777, filed on 3 Aug 1990,
RLI
       now patented, Pat. No. US 5064674 which is a continuation-in-part of
       Ser. No. US 1989-297451, filed on 13 Jan 1989, now patented, Pat. No. US
       4954361
DT
       Utility
       Granted
FS
LN.CNT 1314
INCL
       INCLM: 426/580.000
       INCLS: 426/491.000; 426/583.000; 426/585.000; 426/656.000; 426/660.000;
              426/801.000
NCL
       NCLM:
             426/580.000
              426/491.000; 426/583.000; 426/585.000; 426/656.000; 426/660.000;
       NCLS:
              426/801.000
IC
       [5]
       ICM: A23C009-142
       ICS: A23C009-20
       426/491; 426/580; 426/583; 426/585; 426/656; 426/660; 426/801
EXF
=> d 13 1-17 kwic
L3
     ANSWER 1 OF 17 USPATFULL
PΙ
       US 6039978
                               20000321
       WO 9639053 19961212
       The invention is a dietary food enhancement agent for fortifying food
AB
       products. The agent includes a premixed combination of Vitamin
       A, Vitamin B.sub.1, Vitamin B.sub.2, Vitamin B.sub.6, Vitamin
       B.sub.12, Vitamin C, Vitamin D,
       Vitamin E, Vitamin K, Biotin, Calcium, Copper, Folic
       Acid, Iodine, Iron, Magnesium, Manganese, Pantothenic Acid, Phosphorus,
       and Zinc. Further, calcium may be.
SUMM
       The NCI also suggests that diets rich in foods containing
       Vitamin C and Vitamin A from
       fruits and vegetables may also reduce the risk of cancer. Epidemiologic
       studies have shown that diets high in Vitamin A and
       Vitamin C are associated with lower risks of some
       kinds of cancers. Therefore, the NCI recommends consumption of a variety
       of fruits and vegetables, including fruit and vegetable juices that are
       high in Vitamin A and Vitamin C.
       Especially beneficial are cruciferous vegetables which are good sources
       of fiber, as well as vitamins and minerals.
       . . . major sources of dietary fat rather than by eliminating whole
DETD
       categories of foods. For example, by substituting fish, poultry without
       skin, lean meats and low- or non-fat dairy products for high-fat
```

1500

```
TABLE I
```

```
Daily Desired Level of Fortification
Breakfast Lunch Dinner
```

Meal Meal Meal

Nutrient (35%) (30%) (35%)

VITAMIN A, (IU) 1750

1750

VITAMIN D, (IU) 140 120 140

**VITAMIN E,** (IU) 10.5 9 10.5

**VITAMIN C,** (mg) 35 30 35

VITAMIN B.sub.1, (mg) 0.53 0.45 0.53

VITAMIN B.sub.2, (mg) 0.6 0.51 0.6

VITAMIN B.sub.3, (mg) 7 6 7

VITAMIN B.sub.6, (mg) 0.7 0.6 0.7

VITAMIN B.sub.12, (mcg) 2.1 1.8 2.1

BIOTIN, (mcg) 105 90. . .

DETD

TABLE III

# U.S. Recommended Dietary Allowance (USRDA) NUTRIENT USRDA

VITAMIN A

5000 IU

VITAMIN B.sub.1 1.5 mg

VITAMIN B.sub.2 1.7 mg

VITAMIN B.sub.3 20 mg NE.sup.1

VITAMIN B.sub.6 2 mg

VITAMIN B.sub.12 6 mcg

VITAMIN C 60 mg

VITAMIN D 400 IU

VITAMIN E 30 IU

VITAMIN K 80 mcg

BIOTIN 300 mcg

CALCIUM 1000 mg COPPER 2 mg

FOLIC ACID 400 mcg

IODINE.

DETD

TABLE IV

#### DFEA Compositions

#### CONCENTRATION

# NUTRIENT RANGE

VITAMIN A 1125-9900

VITAMIN B.sub.1 0.41-2.07 mg

VITAMIN B.sub.2 0.23-2.24 mg

VITAMIN B.sub.3 6.3-25.3 mg NE

VITAMIN B.sub.6 0.54-2.75 mg

VITAMIN B.sub.12 1.08-8.58 mcg

**VITAMIN C** 31.5-330 mg

**VITAMIN D** 36-682 IU

VITAMIN E 9.45-49.5 IU

VITAMIN K 0-110 mcg

BIOTIN 94.5-412.5 mcg

CALCIUM 108-1333.2 mg

COPPER 0.95-3.63 mg

FOLIC ACID 126-660 mcg

IODINE.

DETD

TABLE VIII

9000 ΙU Vitamin A VITAMIN A Palmitate VITAMIN B.sub.1 1.88 mg Thiamine Mononitrate VITAMIN B.sub.2 2.04 mg Riboflavin VITAMIN B. sub. 3 23 mg NE Niacinamide VITAMIN B.sub.6 2.5 mg Pyridoxine Hydrochloride VITAMIN B.sub.12 7.8 mcg Vitamin B.sub.12 VITAMIN C 300 mg Ascorbic Acid VITAMIN D 620 IU Vitamm D.sub.3 VITAMIN E 45 IU Vitamin E Acetate VITAMIN K 100 mcg Vitamin K.sub.1 BIOTIN 375 mcg Biotin CALCIUM 1212 mg Calcium Citrate/ Dicalcium Phosphate COPPER 3.3. . . . humidity, e.g. in a range of about 35 to 75% RH, to produce a DETD homogenous vitamin mix: 36 mg of Vitamin A Palmitate (250 micron spray dried); 300 mg of Ascorbic Acid; 6.2 mg of Vitamin D.sub.3 -100 S.D.; 90 mg of Vitamin E acetate 50% (CWS/F); 10 mg of Vitamin K.sub.1, 1% (spray dried); 1.88 mg of Thiamine Mononitrate; 2.04 mg of Riboflavin;. DETD TABLE IX Vitamin and Mineral Mixture (Cereals) CONCENTRATION FORM NUTRIENT 2500 ΙU Vitamin A VITAMIN A Palmitate VITAMIN B.sub.1 0.59 mg Thiamine Mononitrate VITAMIN B.sub.2 0.32 mg Riboflavin VITAMIN B.sub.3 7.7 mg NE Niacinamide VITAMIN B.sub.6 0.84 mg Pyridoxine Hydrochloride VITAMIN B.sub.12 2.4 mcg Vitamin B.sub.12 VITAMIN C 140 mg Ascorbic Acid/Sodium Ascorbate VITAMIN D 80 IU Vitamin D.sub.3 VITAMIN E 15.75 IU Vitamin E Acetate VITAMIN K 35 mcg Vitamin K.sub.1 BIOTIN 141.75 mcg Biotin CALCIUM 123.6 mg Calcium Carbonate COPPER 1.16 mg Copper. . . . humidity, e.g. in a range of about 35 to 75% RH, to produce a DETD homogenous vitamin mix: 10 mg of Vitamin A Palmitate (250 micron spray dried); 140 mg of Ascorbic Acid; 0.8 mg of Vitamin D.sub.3 -100 S.D.; 31.5 mg of Vitamin E acetate 50% (CWS/F); 3.5 mg of Vitamin K.sub.1, 1% (spray dried); 0.59 mg of Thiamine Mononitrate; 0.32 mg of Riboflavin;. TABLE X DETD Vitamin and Mineral Mixture (Soups and Other Retorted Meals) NUTRIENT CONCENTRATION FORM

VITAMIN A 9000 IU Vitamin A
Palmitate
VITAMIN B.sub.1 2.63 mg Thiamine Mononitrate

```
VITAMIN B.sub.2 2.04 mg Riboflavin
   VITAMIN B.sub.3 23 mg NE Niacinamide
  VITAMIN B.sub.6 2.5 mg Pyridoxine
     Hydrochloride
  VITAMIN B.sub.12 7.8 mcg Vitamin B.sub.12
    VITAMIN C 300 mg Ascorbic Acid
    VITAMIN D 620 IU Vitamin D.sub.3
    VITAMIN E 45 IU Vitamin E Acetate
  VITAMIN K 100 mcg Vitamin K.sub.1
  BIOTIN 375 mcg Biotin
  CALCIUM 1212 mg Calcium
     Citrate/Dicalcium
     Phosphate
  COPPER 3.3 mg.
DETD
                      TABLE XI
Garlic Roll
                        Fortification
 Nutrient Level
  VITAMIN A, (IU)
    VITAMIN D, (IU) 155
  VITAMIN B, (IU) 11.25
    VITAMIN C, (mg) 75
  VITAMIN B.sub.1, (mg) 0.47
  VITAMIN B.sub.2, (mg) 0.51
    VITAMIN B.sub.3, (mg NE) 5.75
  VITAMIN B.sub.6, (mg) 0.63
  VITAMIN B.sub.12, (mcg) 1.95
  BIOTIN, (mcg) 93.75
  FOLIC ACID, (mcg) 150
  PANTOTHENIC ACID, .
DETD
                      TABLE XII
Raisin Bran Cereal
                        Fortification
 Nutrient Level
  VITAMIN A, (IU)
   VITAMIN D, (IU) 80
  VITAMIN B, (IU) 15.75
    VITAMIN C, (mg) 140
  VITAMIN B.sub.1, (mg) 0.59
 VITAMIN B.sub.2, (mg) 0.32
VITAMIN B.sub.2, (mg NE) 7.7
  VITAMIN B.sub.6, (mg) 0.84
  VITAMIN.
DETD
                      TABLE XIII
Apple Crisp
                        Fortification
  Nutrient Level
                     1620
  VITAMIN A, (IU)
    VITAMIN D, (IU) 111.6
    VITAMIN E, (IU) 8.1
    VITAMIN C, (mg) 54
  VITAMIN B.sub.1, (mg) 0.34
  VITAMIN B.sub.2, (mg) 0.37
    VITAMIN B.sub.3, (mg NE) 4.14
  VITAMIN B.sub.6, (mg) 0.45
  VITAMIN B.sub.12, (mcg) 1.4
```

```
BIOTIN, (mcg) 67.5
 FOLIC ACID, (mcg) 108
 PANTOTHENIC ACID, .
                     TABLE XIV
Whipped Potatoes
                        Fortification
 Nutrient Level
 VITAMIN A, (IU)
                     1080
   VITAMIN D, (IU) 74.4
   VITAMIN E, (IU) 5.4
   VITAMIN C, (mg) 36
 VITAMIN B.sub.1, (mg) 0.23
 VITAMIN B.sub.2, (mg) 0.25
    VITAMIN B.sub.3, (mg NE) 2.76
 VITAMIN B.sub.6, (mg) 0.3
 VITAMIN B.sub.12, (mcg) 0.94
 BIOTIN, (mcg) 45
  FOLIC ACID, (mcg) 72
  PANTOTHENIC ACID, . .
                     TABLE XV
DETD
Orange Juice Drink
                       Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     1800
   VITAMIN D, (IU) 124
    VITAMIN E, (IU) 9
    VITAMIN C, (mg) 60
 VITAMIN B.sub.1, (mg) 0.38
  VITAMIN B.sub.2, (mg) 0.41
    VITAMIN B. sub. 3, (mg NE) 4.6
  VITAMIN B.sub.6, (mg) 0.5
  VITAMIN B.sub.12, (mcg) 1.56
  BIOTIN, (mcg) 75
  FOLIC ACID, (mcg) 120
  PANTOTHENIC ACID,.
DETD
                      TABLE XVI
Vegetable Soup
                        Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     2700
    VITAMIN D, (IU) 186
    VITAMIN E, (IU) 13.5 VITAMIN C, (mg) 90
  VITAMIN B.sub.1, (mg) 0.79
  VITAMIN B.sub.2, (mg) 0.61
    VITAMIN B.sub.3, (mg NE) 6.9
  VITAMIN B.sub.6, (mg) 0.75
  VITAMIN B.sub.12, (mcg) 2.34
  BIOTIN, (mcg) 112.1
  FOLIC ACID, (mcg) 180
  PANTOTHENIC ACID,.
DETD
                      TABLE XVII
```

Fruit Sauce

Fortification

Nutrient Level

```
VITAMIN A, (IU)
                     450
    VITAMIN D, (IU) 31
    VITAMIN E, (IU) 2.25
    VITAMIN C, (mg) 15
  VITAMIN B.sub.1, (mg) 0.09
  VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B. sub. 3, (mg NE) 1.15
  VITAMIN B.sub.6, (mg) 0.13
  VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID,.
DETD
                     TABLE XVIII
Bagel
                       Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     450
    VITAMIN D, (IU) 31
    VITAMIN E, (IU) 2.25
    VITAMIN C, (mg) 15
  VITAMIN B.sub.1, (mg) 0.09
  VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B.sub.3, (mg NE) 1.15
  VITAMIN B.sub.6, (mg) 0.13
  VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID,.
                     TABLE XIX
DETD
Salisbury Steak
                       Fortification
  Nutrient Level
                     2700
  VITAMIN A, (IU)
    VITAMIN D, (IU) 186
    VITAMIN E, (IU) 13.5
    VITAMIN C, (mg) 90
  VITAMIN B.sub.1, (mg) 0.54
  VITAMIN B.sub.2, (mg) 0.61
    VITAMIN B.sub.3, (mg NE) 6.9
  VITAMIN B.sub.6, (mg) 0.75
  VITAMIN B.sub.12, (mcg) 2.34
  BIOTIN, (mcg) 112.1
  FOLIC ACID, (mcg) 180
  PANTOTHEMC ACID, .
DETD
                     TABLE XX
Salisbury Steak Gravy
                       Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     450
    VITAMIN D, (IU) 31
    VITAMIN E, (IU) 2.25
    VITAMIN C, (mg) 15
  VITAMIN B.sub.1, (mg) 0.09
  VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B.sub.3, (mg NE) 1.15
```

```
VITAMIN B.sub.6, (mg) 0.13
 VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID,.
                                                  7 7 6
DETD
  Sugar (g) 18 33 35 23
  Protein (g) 21 14 16 13
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
  (USRDA)
 Vitamin A
              35
                                35
                                        35
   Vitamin C 55 55 55 55
 Calcium 40 40 40 40
  Iron 35 35 35 35
   Vitamin D 35 35 35 35
    Vitamin E 35 35 35 35
 Thiamine 35 35 35 35
  Riboflavin 35 35 35 35
 Niacin 35 35 35 35
 Vitamin.
                                                   7 5 7
DETD
  Sugar (g) 9 11 15 11
  Protein (g) 19 26 20 20
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
  (USRDA)
                             30
                                    30
                     30
 Vitamin A
              30
    Vitamin C 50 50 50 50
  Calcium 35 35 35 35
  Iron 30 30 30 30
   Vitamin D 30 30 30 30
    Vitamin E 30 30 30 30
 Thiamine 30 30 30 30
  Riboflavin 30 30 30 30
 Niacin 30 30 30 30
 Vitamin.
DETD
  Sugar (g) 7 8 6 13 18
  Protein (g) 26 24 31 27 33
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
  (USRDA)
                                  35
                                         35
 Vitamin A
              35
                     35
   Vitamin C 55 55 55 55 55
 Calcium 40 40 40 40 40
 Iron 35 35 35 35
   Vitamin D 35 35 35 35
    Vitamin E 35 35 35 35 35
  Thiamine 35 35 35 35 35
  Riboflavin 35 35 35 35 35
 Niacin 35 35.
DETD
  Sugar (g) 12 10 11 19 15
  Protein (g) 27 28 32 29 25
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
  (USRDA)
                     35
                           35
                                   35
                                         35
              35
 Vitamin A
    Vitamin C 55 55 55 55 55
  Calcium 40 40 40 40 40
  Iron 35 35 35 35
   Vitamin D 35 35 35 35
    Vitamin E 35 35 35 35 35
  Thiamine 35 35 35 35
  Riboflavin 35 35 35 35 35
```

```
Niacin 35 35.
                                                 1 3 2
DETD
  Sugar (g) 2 1 9 11
  Protein (g) 6 5 11 10
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
  (USRDA)
 Vitamin A
   Vitamin C 4 4 4 4
  Calcium 4 4 4 4
  Iron 4 4 4 4
   Vitamin D 4 4 4 4
   Vitamin E 4 4 4 4
  Thiamine 4 4 4 4
  Riboflavin 4 4 4 4
 Niacin 4 4 4 4
  Vitamin.
DETD
              life. The trial was also to monitor the safety of the Prepared
      Diet by monitoring nutritional intake in plasma vitamins (
      Vitamin A and Vitamin D) and
      mineral (iron), and trace minerals levels.
CLM
      What is claimed is:
       2. The agent of claim 1, wherein said premixed combination further
       comprises Vitamin A, Vitamin B.sub.1, Vitamin
       B.sub.2, Vitamin B.sub.3,
      Vitamin B.sub.6, Vitamin B.sub.12, Vitamin C,
      Vitamin D, Vitamin E, Vitamin K,
      biotin, copper, folic acid, iodine, iron, manganese, pantothenic acid,
      and zinc.
       4. The agent of claim 3, wherein said premixed combination further
       comprises Vitamin A, Vitamin B.sub.1, Vitamin
       B.sub.2, Vitamin B.sub.3,
      Vitamin B.sub.6, Vitamin B.sub.12, Vitamin C,
      Vitamin D, Vitamin E, biotin
       calcium, copper, folic acid, iodine, iron, manganese, pantothenic acid,
       and zinc.
          and stable dietary food enhancement agent for fortifying frozen or
       retorted food products comprising a premixed combination of sources of
       Vitamin A, Vitamin B.sub.1, Vitamin B.sub.2,
       Vitamin B.sub.3, Vitamin B.sub.6,
       Vitamin B.sub.12, Vitamin C, Vitamin
      D, Vitamin E, Vitamin K, biotin, calcium,
       copper, folic acid, iodine, iron, magnesium, manganese, pantothenic
       acid, phosphorus, and zinc, wherein a daily portion in a range of 7.9 to
       10 grams comprises: at least about 9000 IU Vitamin A
       ; at least about 1.88 mg Vitamin B.sub.1 ; at least about 2.04 mg
       Vitamin B.sub.2; at least about 23 mg Vitamin B.
       sub.3 (Niacinamide); at least about 2.5 mg Vitamin
       B.sub.6; at least about 7.8 mcg Vitamin B.sub.12; at least about 375
       mcg biotin; at least about 1212 mg calcium; at least about 300 mg
       Vitamin C; at least about 3.3 mg copper; at least
       about 620 IU Vitamin D; at least about 45 IU
       Vitamin E; at least about 600 mcg folic acid; at least
       about 172.5 mcg iodine; in a range of 5.67 to 20.79.
          powdered, freeflowing, and stable dietary food enhancement agent for
       fortifying cereal food products comprising a premixed combination of
       sources of Vitamin A, Vitamin B.sub.1, Vitamin
       B.sub.2, Vitamin B.sub.3,
       Vitamin B.sub.6, Vitamin B.sub.12, Vitamin C,
       Vitamin D, Vitamin E, Vitamin K,
       biotin, calcium, copper, folic acid, iodine, iron, magnesium, manganese,
```

pantothenic acid, phosphorus, and zinc, wherein a daily portion in a range of 0.86 to 1.6 grams comprises: about 2500 IU Vitamin A; about 0.59 mg Vitamin B.sub.1; about 0.32 mg Vitamin B.sub.2; about 7.7 mg Vitamin B.sub.3 (Niacinamide); about 0.84 mg Vitamin B.sub.6; about 2.4 mcg Vitamin B.sub.12; about 141.75 mcg biotin; about 140 mg Vitamin C; about 123.6 mg calcium; about 1.16 mg copper; about 80 IU Vitamin D; about 15.75 IU Vitamin E; about 210 mcg folic acid; about 60.38 mcg iodine; about 6.62 mg iron; about 4.5 mg pantothenic acid; about 38.63. . .

L3 ANSWER 2 OF 17 USPATFULL

PI US'5994295

19991130

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SUMM The NCI also suggests that diets rich in foods containing

Vitamin C and Vitamin A from

fruits and vegetables may also reduce the risk of cancer. Epidemiologic studies have shown that diets high in  $Vitamin\ A$  and

Vitamin C are associated with lower risks of some

kinds of cancers. Therefore, the NCI recommends consumption of a variety of fruits and vegetables, including fruit and vegetable juices that are high in Vitamin A and Vitamin C.

Especially beneficial are cruciferous vegetables which are good sources of fiber, as well as vitamins and minerals.

DETD

. . . major sources of dietary fat rather than by eliminating whole categories of foods. For example, by substituting fish, poultry without skin, lean meats and low- or non-fat dairy products for high-fat foods, a patient may lower total fat and SFA intake. . .

DETD

TABLE I

Daily Desired Level of Fortification Breakfast Meal

Lunch Meal

Dinner Meal

Nutrient (35%) (30%) (35%)

VITAMIN A, (IU)

1750 1500

1750

VITAMIN D, (IU) 140 120 140

VITAMIN E, (IU) 10.5 9 10.5

**VITAMIN C,** (mg) 35 30 35

VITAMIN B.sub.1, (mg) 0.53 0.45 0.53

VITAMIN B.sub.2, (mg) 0.6 0.51 0.6

VITAMIN B.sub.3, (mg) 7 6 7

VITAMIN B.sub.6, (mg) 0.7 0.6 0.7

VITAMIN B.sub.12, (mcg) 2.1 1.8 2.1

BIOTIN, (mcg) 105 90.

CTEC

TABLE III

U.S. Recommended Dietary Allowance USRDA)
NUTRIENT USRDA

VITAMIN A 5000 IU

VITAMIN B.sub.1 1.5 mg

VITAMIN B.sub.2 1.7 mg

VITAMIN B.sub.3 20 mg NE.sup.1

VITAMIN B.sub.6 2 mg

VITAMIN B.sub.12 6 mcg

VITAMIN C 60 mg

VITAMIN D 400 IU

VITAMIN E 30 IU

VITAMIN K NONE ESTABLISHED

BIOTIN 300 mcg

CALCIUM 1000 mg COPPER 2 mg FOLIC ACID 400 mcg IODINE. TABLE IV DETD DFEA Compositions CONCENTRATION NUTRIENT RANGE 1125-9900 IU VITAMIN A VITAMIN B.sub.1 0.41-2.07 mg VITAMIN B.sub.2 0.23-2.24 mg VITAMIN B. sub. 3 6.3-25.3 mg NE VITAMIN B.sub.6 0.54-2.75 mg VITAMIN B.sub.12 1.08-8.58 mcg VITAMIN C 31.5-330 mg VITAMIN D 36-682 IU **VITAMIN E 9.45-49.5 IU** VITAMIN K 0-110 mcg BIOTIN 94.5-412.5 mcg CALCIUM 108-1333.2 mg COPPER 0.95-3.63 mg FOLIC ACID 126-660 mcg IODINE. . . TABLE VIII DETD Vitamin and Mineral Mixture (Frozen Foods) CONCENTRATION NUTRIENT FORM 9000 IU VITAMIN A Vitamin A Palmitate VITAMIN B.sub.1 1.88 mg Thiamine Mononitrate VITAMIN B.sub.2 2.04 mg Riboflavin VITAMIN B.sub.3 23 mg NE Niacinamide VITAMIN B.sub.6 2.5 mg Pyridoxine Hydrochloride VITAMIN B.sub.12 7.8 mcg Vitamin B.sub.12 VITAMIN C 300 mg Ascorbic Acid VITAMIN D 620 IU Vitamin D.sub.3 VITAMIN E 45 IU Vitamin E Acetate VITAMIN K 100 mcg Vitamin K.sub.1 BIOTIN 375 mcg Biotin CALCIUM 1212 mg Calcium Citrate/ Dicalcium Phosphate COPPER 3.3. . . . humidity, e.g. in a range of about 35 to 75% RH, to produce a homogenous vitamin mix: 36 mg of  $\bf Vitamin~\bf A$  Palmitate DETD (250 micron spray dried); 300 mg of Ascorbic Acid; 6.2 mg of Vitamin D.sub.3 -100 S.D.; 90 mg of Vitamin E acetate 50% (CWS/F); 10 mg of Vitamin K.sub.1, 1% (spray dried); 1.88 mg of Thiamine Mononitrate; 2.04 mg of Riboflavin;. DETD TABLE IX

Vitamin and Mineral Mixture (Cereals)
NUTRIENT CONCENTRATION FORM

VITAMIN A 2500 IU Vitamin A
Palmitate

VITAMIN B.sub.1 0.59 mg Thiamine Mononitrate VITAMIN B.sub.2 0.32 mg Riboflavin

```
VITAMIN B.sub.6 0.84 mg Pyridoxine Hydro-
    chloride
  VITAMIN B.sub.12 2.4 mcg Vitamin B.sub.12
   VITAMIN C 140 mg Ascorbic Acid/Sodium
   Ascorbate
   VITAMIN D 80 IU Vitamin D.sub.3
   VITAMIN E 15.75 IU Vitamin E Acetate
  BIOTIN 141.75 mcg Biotin
  CALCIUM 123.6 mg Calcium Carbonate
  COPPER 1.16 mg Copper Gluconate
  FOLIC ACID 210 mcg Folic.
                     TABLE X
DETD
Vitamin and Mineral Mixture (Soups and Other Retorted Meals)
  NUTRIENT
                 CONCENTRATION FORM
               9000 IU
  VITAMIN A
                            Vitamin A
       Palmitate
  VITAMIN B.sub.1 2.63 mg Thiamine Mononitrate
  VITAMIN B.sub.2 2.04 mg Riboflavin
   VITAMIN B.sub.3 23 mg NE Niacinamide
  VITAMIN B.sub.6 2.5 mg Pyridoxine Hydro-
    chloride
  VITAMIN B.sub.12 7.8 mcg Vitamin B.sub.12
   VITAMIN C 300 mg Ascorbic Acid
   VITAMIN D 620 IU Vitamin D.sub.3
   VITAMIN E 45 IU Vitamin E Acetate
  VITAMIN K 100 mcg Vitamin K.sub.1
  BIOTIN 375 mcg Biotin
  CALCIUM 1212 mg Calcium Citrate/
    Dicalcium Phosphate
  COPPER 3.3.
DETD
                     TABLE XI
Garlic Roll
                   Fortification
Nutrient
                   Level
  VITAMIN A, (IU)
   VITAMIN D, (IU) 155
   VITAMIN E, (IU) 11.25
   VITAMIN C, (mg) 75
  VITAMIN B.sub.1, (mg) 0.47
  VITAMIN B.sub.2, (mg) 0.51
    VITAMIN B.sub.3, (mg NE) 5.75
  VITAMIN B.sub.6, (mg) 0.63
  VITAMIN B.sub.12, (mcg) 1.95
  BIOTIN, (mcg) 93.75
  FOLIC ACID, (mcg) 150
  PANTOTHNIC ACID,.
DETD
                     TABLE XII
Raisin Bran Cereal
                       Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     2500
    VITAMIN D., (IU) 80
   VITAMIN E, (IU) 15.75
```

VITAMIN C, (mg) 140 VITAMIN B.sub.1, (mg) 0.59

VITAMIN B.sub.3 7.7 mg NE Niacinamide

```
VITAMIN B.sub.2, (mg) 0.32
   VITAMIN B.sub.3, (mg NE) 7.7
 VITAMIN B.sub.6, (mg) 0.84
  VITAMIN B.sub.12, (mcg) 2.4
  BIOTIN, (mcg) 141.75
  FOLIC ACID, (mcg) 210
  PANTOTHENIC ACID, .
                      TABLE XIII
Apple Crisp
                        Fortification
 Nutrient Level
  VITAMIN A, (IU)
                     1620
    VITAMIN D, (IU) 111.6
    VITAMIN E, (IU) 8.1
    VITAMIN C, (mg) 54
  VITAMIN B.sub.1, (mg) 0.34
  VITAMIN B.sub.2, (mg) 0.37
    VITAMIN B.sub.3, (mg NE) 4.14
 VITAMIN B.sub.6, (mg) 0.45
  VITAMIN B.sub.12, (mcg) 1.4
  BIOTIN, (mcg) 67.5
 FOLIC ACID, (mcg) 108 PANTOTHENIC ACID,...
                      TABLE XIV
DETD
Whipped Potatoes
                        Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     1080
    VITAMIN D, (IU) 74.4
    VITAMIN E, (IU) 5.4
    VITAMIN C, (mg) 36
  VITAMIN B.sub.1, (mg) 0.23
  VITAMIN B.sub.2, (mg) 0.25
    VITAMIN B. sub. 3, (mg NE) 2.76
  VITAMIN B.sub.6, (mg) 0.3
  VITAMIN B.sub.12, (mcg) 0.94
  BIOTIN, (mcg) 45
  FOLIC ACID, (mcg) 72
  PANTOTHENIC ACID,.
                      TABLE XV
DETD
Orange Juice Drink
                        Fortification
  Nutrient Level
  VITAMIN A, (IU)
    VITAMIN D, (IU) 124
    VITAMIN E, (IU) 9
    VITAMIN C, (mg) 60
  VITAMIN B.sub.1, (mg) 0.38
  VITAMIN B.sub.2, (mg) 0.41
    VITAMIN B.sub.3, (mg NE) 4.6
  VITAMIN B.sub.6, (mg) 0.5
  VITAMIN B.sub.12, (mcg) 1.56
  BIOTIN, (mcg) 75
  FOLIC ACID, (mcg) 120
  PANTOTHENIC ACID,.
DETD
                      TABLE XVI
```

```
Vegetable Soup

    Fortification

 Nutrient Level
 VITAMIN A, (IU)
                     2700
   VITAMIN D, (IU) 186
   VITAMIN E, (IU) 13.5
   VITAMIN C, (mg) 90
 VITAMIN B.sub.1, (mg) 0.79
 VITAMIN B.sub.2, (mg) 0.61
   VITAMIN B.sub.3, (mg NE) 6.9
 VITAMIN B.sub.6, (mg) 0.75
 VITAMIN B.sub.12, (mcg) 2.34
 BIOTIN, (mcg) 112.1
  FOLIC ACID, (mcg) 180
  PANTOTHENIC ACID,.
DETD
                     TABLE XVII
Fruit Sauce
                       Fortification
 Nutrient Level
 VITAMIN A, (IU)
   VITAMIN D, (IU) 31
   VITAMIN E, (IU) 2.25
   VITAMIN C, (mg) 15
  VITAMIN B.sub.1, (mg) 0.09
 VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B.sub.3, (mg NE) 1.15
 VITAMIN B.sub.6, (mg) 0.13
 VITAMIN B.sub.12, (mcg) 0.39
 BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID, .
DETD
                     TABLE XVIII
Bagel
                       Fortification
 Nutrient Level
  VITAMIN A, (IU)
   VITAMIN D, (IU) 31
   VITAMIN E, (IU) 2.25
   VITAMIN C, (mg) 15
 VITAMIN B.sub.1, (mg) 0.09
 VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B. sub. 3, (mg NE) 1.15
  VITAMIN B.sub.6, (mg) 0.13
  VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID, .
DETD
                     TABLE XIX
Salisbury Steak
                       Fortification
 Nutrient Level
                     2700
  VITAMIN A, (IU)
    VITAMIN D, (IU) 186
    VITAMIN E, (IU) 13.5
```

```
VITAMIN C, (mg) 90
 VITAMIN B.sub.1, (mg) 0.54
 VITAMIN B.sub.2, (mg) 0.61
   VITAMIN B.sub.3, (mg NE) 6.9
 VITAMIN B.sub.6, (mg) 0.75
 VITAMIN B.sub.12, (mcg) 2.34
 BIOTIN, (mcg) 112.1
 FOLIC ACID, (mcg) 180
  PANTOTHENIC ACID, .
                     TABLE XX
Salisbury Steak Gravy
                       Fortification
 Nutrient Level
 VITAMIN A, (IU)
                    450
   VITAMIN D, (IU) 31
   VITAMIN E, (IU) 2.25
   VITAMIN C, (mg) 15
 VITAMIN B.sub.1, (mg) 0.09
  VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B.sub.3, (mg NE) 1.15
  VITAMIN B.sub.6, (mg) 0.13
  VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID, .
DETD
  (g)
  Sugar (g) 18 33 35 23
  Protein (g) 21 14 16 13
PERCENTAGE OF U.S. RECOMMENDED DIETARY
  ALLOWANCES (USRDA)
                                35
                                         35
    Vitamin A 35
                        35
    Vitamin C 55 55 55 55
  Calcium 40 40 40 40
  Iron 35 35 35 35
    Vitamin D 35 35 35
    Vitamin E 35 35 35 35
  Thiamine 35 35 35
  Riboflavin 35 35 35 35
  Niacin 35 35 35 35
  Vitamin. .
DETD
                             Fiber (g)
  Sugar (g) 9 11 15 11
  Protein (g) 19 26 20 20
PERCENTAGE OF U.S. RECOMMENDED DIETARY
  ALLOWANCES (USRDA)
                                 30
                                          30
    Vitamin A 30
    Vitamin C 50 50 50 50
  Calcium 35 35 35 35
  Iron 30 30 30 30
    Vitamin D 30 30 30 30
    Vitamin E 30 30 30 30
  Thiamine 30 30 30 30
  Riboflavin 30 30 30 30
  Niacin 30 30 30 30
  Vitamin.
DETD
  Sugar (g) 7 8 6 13 18
  Protein (q) 26 24 31 27 33
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
```

```
35
                                        35
                   35
 Vitamin A 35
   Vitamin C 55 55 55 55 55
 Calcium 40 40 40 40 40
 Iron 35 35 35 35 35
   Vitamin D 35 35 35 35
   Vitamin E 35 35 35 35 35
 Thiamine 35 35 35 35 35
 Riboflavin 35 35 35 35
 Niacin 35 35.
 Sugar (g) 12 10 11 19 15
 Protein (g) 27 28 32 29 25
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
 Vitamin A 35
                   35 35
                                 35
                                        35
   Vitamin C 55 55 55 55 55
 Calcium 40 40 40 40 40
 Iron 35 35 35 35
   Vitamin D 35 35 35 35 35
   Vitamin E 35 35 35 35
 Thiamine 35 35 35 35
 Riboflavin 35 35 35 35 35
 Niacin 35 35.
DETD
 Sugar (g) 2 1 9 11
  Protein (g) 6 5 11 10
PERCENTAGE OF U.S. RECOMMENDED DIETARY
 ALLOWANCES (USRDA)
   Vitamin A 4
   Vitamin C 4 4 & 4
 Calcium 4 4 4 4
  Iron 4 4 4 4
   Vitamin D 4 4 4 4
   Vitamin E 4 4 4 4
  Thiamine 4 4 4 4
  Riboflavin 4 4 4 4
 Niacin 4 4 4 4
 Vitamin.
               life. The trial was also to monitor the safety of the Prepared
DETD
      Diet by monitoring nutritional intake in plasma vitamins (
      Vitamin A and Vitamin D) and
      mineral (iron), and trace minerals levels.
    ANSWER 3 OF 17 USPATFULL
L3
                                                                    <--
                               19991102
PΙ
      US 5977059
       The NCI also suggests that diets rich in foods containing
SUMM
      Vitamin C and Vitamin A from
       fruits and vegetables may also reduce the risk of cancer. Epidemiologic
       studies have shown that diets high in Vitamin A and
       Vitamin C are associated with lower risks of some
       kinds of cancers. Therefore, the NCI recommends consumption of a variety
       of fruits and vegetables, including fruit and vegetable juices that are
       high in Vitamin A and Vitamin C.
       Especially beneficial are cruciferous vegetables which are good sources
       of fiber, as well as vitamins and minerals.
       . . . major sources of dietary fat rather than by eliminating whole
DETD
       categories of foods. For example, by substituting fish, poultry without
       skin, lean meats and low- or non-fat dairy products for high-fat
       foods, a patient may lower total fat and SFA intake. . .
                     TABLE I
DETD
```

(USRDA)

#### Breakfast Meal

Lunch Meal

Dinner Meal

Nutrient (35%) (30%) (35%)

VITAMIN A, (IU) 1750 1750 1500 VITAMIN D, (IU) 140 120 140 **VITAMIN E,** (IU) 10.5 9 10.5 VITAMIN C, (mg) 35 30 35 VITAMIN B.sub.1, (mg) 0.53 0.45 0.53 VITAMIN B.sub.2, (mg) 0.6 0.51 0.6 **VITAMIN B. sub. 3,** (mg) 7 6 7 VITAMIN B6, (mg) 0.7 0.6. 0.7 VITAMIN B.sub.12, (mcg) 2.1 1.8 2.1 BIOTIN, (mcg) 105 90. . . TABLE III DETD

U.S. Recommended Dietary Allowance (USRDA) NUTRIENT

5000 IU VITAMIN A VITAMIN B.sub.1 1.5 mg VITAMIN B.sub.2 1.7 mg VITAMIN B. sub. 3 20 mg NE. sup. 1 VITAMIN B.sub.6 2 mg VITAMIN B.sub.12 6 mcg VITAMIN C 60 mg VITAMIN D 400 IU VITAMIN E 30 IU VITAMIN K NONE ESTABLISHED BIOTIN 300 mcg CALCIUM 1000 mg COPPER 2 mg FOLIC ACID 400 mcg

IODINE.

DETD

TABLE IV

DFEA Compositions

CONCENTRATION

NUTRIENT RANGE

1125-9900 IU VITAMIN A VITAMIN B.sub.1 0.41-2.07 mg VITAMIN B.sub.2 0.23-2.24 mg VITAMIN B. sub. 3 6.3-25.3 mg NE VITAMIN B.sub.6 0.54-2.75 mg VITAMIN B.sub.12 1.08-8.58 mcg **VITAMIN C** 31.5-330 mg VITAMIN D 36-682 IU **VITAMIN E** 9.45-49.5 IU VITAMIN K 0-110 mcg BIOTIN 94.5-412.5 mcg CALCIUM 108-1333.2 mg COPPER 0.95-3.63 mg FOLIC ACID 126-660 mcg IODINE. DETD TABLE VIII

Vitamin and Mineral Mixture (Frozen Foods) CONCEN-NUTRIENT TRATION FORM

VITAMIN A 9000 IU Vitamin A

Palmitate

VITAMIN B.sub.1 1.88 mg Thiamine Mononitrate

VITAMIN B.sub.2 2.04 mg Riboflavin

VITAMIN B.sub.3 23 mg NE Niacinamide

VITAMIN B.sub.6 2.5 mg Pyridoxine Hydrochloride

VITAMIN B.sub.12 7.8 mcg Vitamin B12

VITAMIN C 300 mg Ascorbic Acid

VITAMIN D 620 IU Vitamin D.sub.3

VITAMIN E 45 IU Vitainin E Acetate

VITAMIN K 100 mcg Vitamin K.sub.1

BIOTIN 375 mcg Biotin

CALCIUM 1212 mg Calcium Citrate/Dicalcium

DETD . . . humidity, e.g. in a range of about 35 to 75% RH, to produce a homogenous vitamin mix: 36 mg of Vitamin A Palmitate (250 micron spray dried); 300 mg of Ascorbic Acid; 6.2 mg of Vitamin D.sub.3 --100 S.D.; 90 mg of Vitamin E acetate 50% (CWS/F); 10 mg of Vitamin K.sub.1, 1% (spray dried); 1.88 mg of Thiamine Mononitrate; 2.04 mg of Riboflavin; . .

Vitmnin and Mineral Mixture (Cereals)

NUTRIENT CENTRATION FORM

# VITAMIN A 2500 IU Vitamin A

Palmitate

VITAMIN B.sub.1 0.59 mg Thiamine Mononitrate

TABLE IX

VITAMIN B.sub.2 0.32 mg Riboflavin

VITAMIN B.sub.3 7.7 mg NE Niacinamide

VITAMIN B.sub.6 0.84 mg Pyridoxine Hydrochloride

VITAMIN B.sub.12 2.4 mcg Vitamin B.sub.12

VITAMIN C 140 mg Ascorbic Acid/Sodium

Ascorbate

VITAMIN D 80 IU Vitamin D. sub. 3

VITAMIN E 15.75 IU Vitamin E Acetate

BIOTIN 141.75 mcg Biotin

CALCIUM 123.6 mg Calcium Carbonate

COPPER 1.16 mg Copper Gluconate

FOLIC ACID 210 mcg Folic.

DETD

DETD

TABLE X

Vitamin and Mineral Mixture (Soups and Other Retorted Meals)
CON-

NUTRIENT CENTRATION FORM

### VITAMIN A 9000 IU Vitamin A

Palmitate

VITAMIN B.sub.1 2.63 mg Thiamine Mononitrate

VITAMIN B.sub.2 2.04 mg Riboflavin

VITAMIN B.sub.3 23 mg NE Niacinamide

VITAMIN B.sub.6 2.5 mg Pyridoxine Hydrochloride

VITAMIN B.sub.12 7.8 mcg Vitamin B.sub.12

VITAMIN C 300 mg Ascorbic Acid

VITAMIN D 620 IU Vitamin D.sub.3

VITAMIN E 45 IU Vitamin E Acetate

VITAMIN K 100 mcg Vitamin K.sub.1

BIOTIN 375 mcg Biotin

CALCIUM 1212 mg Calcium Citrate/Dicalcium

Phosphate

```
COPPER 3.3 mg.
                     TABLE XI
DETD
Garlic Roll
                        Fortification
 Nutrient Level
                     2250
 VITAMIN A, (IU)
   VITAMIN D, (IU) 155
   VITAMIN E, (IU) 11.25
   VITAMIN C, (mg) 75
 VITAMIN B.sub.1, (mg) 0.47
 VITAMIN B.sub.2, (mg) 0.51
   VITAMIN B.sub.3, (mg NE) 5.75
 VITAMIN B.sub.6, (mg) 0.63
 VITAMIN B.sub.12, (mcg) 1.95
 BIOTIN, (mcg) 93.75
  FOLIC ACID, (mcg) 150
  PANTOTHENIC ACID, .
                     TABLE XII
DETD
Raisin Bran Cereal
                       Fortification
 Nutrient Level
 VITAMIN A, (IU)
                     2500
   VITAMIN D, (IU) 80
   VITAMIN E, (IU) 15.75
   VITAMIN C, (mg) 140
 VITAMIN B.sub.1, (mg) 0.59
  VITAMIN B.sub.2, (mg) 0.32
    VITAMIN B. sub. 3, (mg NE) 7.7
  VITAMIN B.sub.6, (mg) 0.84
  VITAMIN B.sub.12, (mcg) 2.4
  BIOTIN, (mcg) 141.75
  FOLIC ACID, (mcg) 210
  PANTOTHENIC ACID, .
                      TABLE XIII
DETD
Apple Crisp
                        Fortification
  Nutrient Level
  VITAMIN A, (IU)
   VITAMIN D, (IU) 111.6
   VITAMIN E, (IU) 8.1
VITAMIN C, (mg) 54
 VITAMIN B.sub.1, (mg) 0.34
  VITAMIN B.sub.2, (mg) 0.37
    VITAMIN B. sub. 3, (mg NE) 4.14
 VITAMIN B.sub.6, (mg) 0.45
  VITAMIN B.sub.12, (mcg) 1.4
  BIOTIN, (mcg) 67.5
  FOLIC ACID, (mcg) 108
  PANTOTHENIC ACID,.
                      TABLE XIV
DETD
Whipped Potatoes
                        Fortification
 Nutrient Level
  VITAMIN A, (IU)
                      1080
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VITAMIN D, (IU) 74.4
    VITAMIN E, (IU) 5.4
    VITAMIN C, (mg) 36
  VITAMIN B.sub.1, (mg) 0.23
 VITAMIN B.sub.2, (mg) 0.25
    VITAMIN B.sub.3, (mg NE) 2.76
  VITAMIN B.sub.6, (mg) 0.3
  VITAMIN B.sub.12, (mcg) 0.94
  BIOTIN, (mcg) 45
  FOLIC ACID, (mcg) 72
  PANTOTHENIC ACID,.
                     TABLE XV
DETD
Orange Juice Drink
                       Fortification
 Nutrient Level
  VITAMIN A, (IU)
    VITAMIN D, (IU) 124
    VITAMIN E, (IU) 9
    VITAMIN C, (mg) 60
  VITAMIN B.sub.1, (mg) 0.38
  VITAMIN B.sub.2, (mg) 0.41
    VITAMIN B.sub.3, (mg NE) 4.6
  VITAMIN B.sub.6, (mg) 0.5
  VITAMIN B.sub.12, (mcg) 1.56
  BIOTIN, (mcg) 75
  FOLIC ACID, (mcg) 120
  PANTOTHENIC ACID, . .
                     TABLE XVI
DETD
Vegetable Soup
                       Fortification
  Nutrient Level
                     2700
  VITAMIN A, (IU)
   VITAMIN D, (IU) 186
    VITAMIN E, (IU) 13.5
    VITAMIN C, (mg) 90
  VITAMIN B.sub.1, (mg) 0.79
  VITAMIN B.sub.2, (mg) 0.61
    VITAMIN B. sub. 3, (mg NE) 6.9
  VITAMIN B.sub.6, (mg) 0.75
  VITAMIN B.sub.12, (mcg) 2.34
  BIOTIN, (mcg) 112.1
  FOLIC ACID, (mcg) 180
  PANTOTHENIC ACID,.
DETD
                     TABLE XVII
Fruit Sauce
                       Fortification
  Nutrient Level
  VITAMIN A, (IU)
    VITAMIN D, (IU) 31
    VITAMIN E, (IU) 2.25
    VITAMIN C, (mg) 15
  VITAMIN B.sub.1, (mg) 0.09
  VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B. sub. 3, (mg NE) 1.15
  VITAMIN B.sub.6, (mg) 0.13
  VITAMIN B.sub.12, (mcg) 0.39
```

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PANTOTHENIC ACID,.
                     TABLE XVIII
Bagel
                       Fortification
 Nutrient Level
 VITAMIN A, (IU)
                     450
   VITAMIN D, (IU) 31
   VITAMIN E, (IU) 2.25
   VITAMIN C, (mg) 15
 VITAMIN B.sub.1, (mg) 0.09
 VITAMIN B.sub.2, (mg) 0.1
   VITAMIN B.sub.3, (mg NE) 1.15
 VITAMIN B.sub.6, (mg) 0.13
 VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID,.
DETD
                     TABLE XIX
Salisbury Steak
                        Fortification
  Nutrient Level
  VITAMIN A, (IU)
                     2700
   VITAMIN D, (IU) 186
    VITAMIN E, (IU) 13.5
   VITAMIN C, (mg) 90
  VITAMIN B.sub.1, (mg) 0.54
  VITAMIN B.sub.2, (mg) 0.61
    VITAMIN B.sub.3, (mg NE) 6.9
 VITAMIN B.sub.6, (mg) 0.75
  VITAMIN B.sub.12, (mcg) 2.34
  BIOTIN, (mcg) 112.1
  FOLIC ACID, (mcg) 180
  PANTOTHENIC ACID, .
DETD
                      TABLE XX
Salisbury Steak Gravy
                        Fortification
 Nutrient Level
  VITAMIN A, (IU)
   VITAMIN D, (IU) 31
   VITAMIN E, (IU) 2.25 VITAMIN C, (mg) 15
  VITAMIN B.sub.1, (mg) 0.09
  VITAMIN B.sub.2, (mg) 0.1
    VITAMIN B.sub.3, (mg NE) 1.15
 VITAMIN B.sub.6, (mg) 0.13
  VITAMIN B.sub.12, (mcg) 0.39
  BIOTIN, (mcg) 18.75
  FOLIC ACID, (mcg) 30
  PANTOTHENIC ACID, .
                                                    7 7 6
DETD
  Sugar (g) 18 33 35 23
  Protein (g) 21 14 16 13
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES (USRDA)
                      35
                                35
                                         35
  Vitamin A 35
```

BIOTIN, (mcg) 18.75 FOLIC ACID, (mcg) 30

```
Vitamin C 55 55 55 55
 Calcium 40 40 40 40
 Iron 35 35 35 35
   Vitamin D 35 35 35 35
   Vitamin E 35 35 35 35
 Thiamine 35 35 35 35
 Riboflavin 35 35 35 35
 Niacin 35 35 35 35
 Vitamin. .
DETD
  Sugar (g) 9 11 15 11
  Protein (g) 19 26 20 20
PERCENTAGE OF U.S. RECOMMENDED
  DIETARY ALLOWANCES (USRDA)
                                           30
   Vitamin A
                  30
                           30 .
                                   30
    Vitamin C 50 50 50 50
 Calcium 35 35 35 35
  Iron 30 30 30 30
   Vitamin D 30 30 30 30
    Vitamin E 30 30 30 30
 Thiamine 30 30 30 30
 Riboflavin 30 30 30 30
  Niacin 30 30 30 30
  Vitamin. .
                                                  27 33
DETD
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES (USRDA)
           GRILLED
                  GRILLED
                       HERB
   BBQ MUSTARD ROASTED POT
   CHICKEN CHICKEN CHICKEN MEATLOAF ROAST
    Vitamin A 35 35 35 35
    Vitamin C 55 55 55 55
  Calcium 40 40 40 40 40
  Iron 35 35 35 35 35
    Vitamin D 35 35 35 35
    Vitamin E 35 35 35 35 35
  Thiamine 35 35 35 35 35
  Riboflavin 35 35 35 35
  Niacin 35 35.
  Sugar (g) 12 10 11 19 15
  Protein (g) 27 28 32 29 25
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES (USRDA)
  Vitamin A 35
                   35
                         35
                                  35
                                         35
    Vitamin C 55 55 55 55 55
  Calcium 40 40 40 40 40
  Iron 35 35 35 35
    Vitamin D 35 35 35 35
    Vitamin E 35 35 35 35
  Thiamine 35 35 35 35
  Riboflavin 35 35 35 35
  Niacin 35 35.
                              3 2
DETD
  Sugar (g) 2 1 9 11
  Protein (q) 6 5 11 10
PERCENTAGE OF U.S. RECOMMENDED
  DIETARY ALLOWANCES (USRDA)
    Vitamin A
    Vitamin C 4 4 4 4
  Calcium 4 4 4 4
```

```
Iron 4 4 4 4
   Vitamin D 4 4 4 4
   Vitamin E 4 4 4 4
  Thiamine 4 4 4 4
  Riboflavin 4 4 4 4
 Niacin 4 4 4 4
 Vitamin.
            . life. The trial was also to monitor the safety of the Prepared
DETD
      Diet by monitoring nutritional intake in plasma vitamins (
      Vitamin A and Vitamin D) and
      mineral (iron), and trace minerals levels.
1.3
    ANSWER 4 OF 17 USPATFULL
PΙ
      US 5976513
                               19991102
      It is well known that exposure to sunlight can pose a number of hazards
SUMM
      to the skin. These damaging effects may result not only from
       sunbathing but also from the sunlight exposure associated with daily
       outdoor activities.. . . a wavelength of from about 290 nm to about
       320 nm. Over the long term, however, malignant changes in the
       skin surface often occur. Numerous epideminologic studies
      demonstrate a strong relationship between sunlight exposure and human
      skin cancer. Another long term hazard of ultraviolet radiation
      is premature aging of the skin, which is primarily caused by
      UVA radiation having a wavelength of from about 320 nm to about 400 nm.
      This condition is characterized by wrinkling and pigment changes of the
       skin, along with other physical changes such as cracking,
       telangiectasis, solar dermatoses, ecchymoses, and loss of elasticity.
      The adverse effects associated.
       . . . care products" refer to health and cosmetic beauty aid products
SUMM
      generally recognized as being formulated for beautifying and grooming
       the skin and hair. For example, personal care products include
       sunscreen products (e.g., lotions, skin creams, etc.),
       cosmetics, toiletries, and over-the-counter pharmaceutical products
      intended for topical usage.
         . . are efficient at absorbing UV radiation in the 290 nm to 320 nm
SUMM
      UVB region such that sunburn of the skin is prevented. They
       are less efficient when it comes to absorbing light which falls in the
       320 nm to 400 nm UVA region, which leaves the skin vulnerable
       to premature skin aging. This deficiency is due in part to the
       limited number of UVA absorbing sunscreen actives which are both
       commercially.
SUMM
            . there is a need for photostabilized compositions suitable for
      providing protection against the harmful effects of UV radiation to
      human skin. In particular, in the personal care industry, a
      need remains for sunscreen products having excellent photostability,
       efficiency, and which provide.
         . . and most preferably from about 2:1 to about 1:1. The present
SUMM
       invention also relates to methods for providing protection to
       skin from the harmful effects of UV radiation by topical
       application of such compositions. Furthermore, the present invention
       relates to methods.
       . . . compositions of the present invention are useful for providing
SUMM
      protection against the harmful effects of ultraviolet radiation,
       especially to human skin. The essential components of these
       compositions are described below. Also included is a nonexclusive
      description of various optional and preferred.
       . . . against erythema. The SPF is defined as the ratio of the
SUMM
      ultraviolet energy required to produce minimal erythema on protected
       skin to that required to produce the same minimal erythema on
       unprotected skin in the same individual. See Federal Register,
       43, No. 166, pp. 38206-38269, Aug. 25, 1978).
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. . . use application. For example, carriers of the present invention

SUMM

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include, but are not limited to, those suitable for application to
skin, hair, nails, animal skin, fur, automobiles,
fabrics, marine vehicles, as well as those suitable for incorporation
into plastics, metals, etc.. Preferably, the carriers of the present
invention are suitable for application to skin (e.g.,
sunscreens, creams, milks, lotions, masks, serums, etc.); hair and fur
(e.g., shampoos, hair setting or treatment gels or lotions,.
lacquers or lotions, etc,); and nails (e.g., polishes, treatments,
etc.). In preferred embodiments, the carrier is suitable for application
to skin which means that the carrier and its components are
suitable for use in contact with skin, hair, fur, and nails
without undue toxicity, incompatibility, instability, allergic response,
and the like within the scope of sound medical. . . and can include
one or more compatible liquid or solid filler diluents or vehicles which
are suitable for application to skin, hair, fur, and nails.
The exact amount of carrier will depend upon the level of the
UVA-absorbing dibenzoylmethane sunscreen active,. . .
. . . etc.), hair care and styling products (e.g., shampoos,
conditioners, gels, mousses, sprays, etc.), topical animal care items
(e.g., shampoos, conditioners, skin treatments, etc.). Any
additional components required to formulate such products vary with
product type and can be routinely chosen by. .
If compositions of the present invention are formulated as an aerosol
and applied to the skin as a spray-on product, a propellant is
added to the composition. Examples of suitable propellants include
chlorofluorinated lower molecular weight.
In a preferred embodiment, where the composition is to be in contact
with human skin, the optional components should be suitable
for application to skin, that is, when incorporated into the
composition they are suitable for use in contact with human skin
without undue toxicity, incompatibility, instability, allergic response,
and the like within the scope of sound medical judgment. The CTFA
Cosmetic Ingredient Handbook, Second Edition (1992) describes a wide
variety of nonlimiting cosmetic and pharmaceutical ingredients commonly
used in the skin care industry, which are suitable for use in
the compositions of the present invention. Examples of these ingredient
classes include: abrasives, absorbents, aesthetic components such as
fragrances, pigments, colorings/colorants, essential oils, skin
sensates, astringents, etc. (e.g., clove oil, menthol, camphor,
eucalyptus oil, eugenol, menthyl lactate, witch hazel distillate),
anti-acne agents, anti-caking agents,. . . and substantivity of the
composition (e.g., copolymer of eicosene and vinyl pyrrolidone),
opacifying agents, pH adjusters, propellants, reducing agents,
sequestrants, skin bleaching and lightening agents (e.g.,
hydroquinone, kojic acid, ascorbic acid, magnesium ascorbyl phosphate,
ascorbyl glucosamine), skin-conditioning agents (e.g.,
humectants, including miscellaneous and occlusive), skin
soothing and/or healing agents (e.g., panthenol and derivatives (e.g.,
ethyl panthenol), aloe vera, pantothenic acid and its derivatives,
allantoin, bisabolol, and dipotassium glycyrrhizinate), skin
treating agents, thickeners, and vitamins and derivatives thereof.
     . such optional components. Preferred compositions optionally
contain one or more materials selected from UVB sunscreen actives,
anti-acne actives, vitamin compounds, skin treating agents,
humectants, moisturizers, skin conditioners, thickening
agents, structuring agents, and emulsifiers.
        These vitamin compounds may be in either natural or synthetic
form. Suitable vitamin compounds include, but are not limited to,
Vitamin A (e.g., beta carotene, retinoic acid,
retinol, retinoids, retinyl palmitate, retinyl proprionate, etc.),
Vitamin B (e.g., niacin, niacinamide, riboflavin, pantothenic acid,
etc.), Vitamin C (e.g., ascorbic acid, etc.),
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SUMM

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SUMM

Vitamin D (e.g., ergosterol, ergocalciferol,
cholecalciferol, etc.), Vitamin E (e.g., tocopherol
acetate, etc.), and Vitamin K (e.g., phytonadione, menadione, phthiocol,
etc.) compounds.

- SUMM In particular, the compositions of the present invention may comprise a safe and effective amount of a **vitamin B.sub** 
  - .3 compound. Vitamin B. sub.
  - 3 compounds are particularly useful for regulating skin condition as described in co-pending U.S. application Ser. No. 08/834,010, filed Apr. 11, 1997 (corresponding to international publication WO 97/39733. . . and still more preferably from about 1% to about 5%, most preferably from about 2% to about 5%, of the vitamin B.sub.3 compound.
- SUMM As used herein, "vitamin B.sub.3 compound" means a compound having the formula: ##STR7## wherein R is --CONH.sub.2 (i.e., niacinamide), --COOH (i.e., nicotinic acid) or --CH.sub.2. . .
- SUMM Exemplary derivatives of the foregoing vitamin B.

  sub.3 compounds include nicotinic acid esters,
  including non-vasodilating esters of nicotinic acid, nicotinyl amino
  acids, nicotinyl alcohol esters of carboxylic acids,...
- SUMM Examples of suitable vitamin B.sub.

  3 compounds are well known in the art and are commercially available from a number of sources, e.g., the Sigma Chemical. .
- SUMM d) Skin Treating Agent
- SUMM The compositions of the present invention may contain one or more skin treating agents. Suitable skin treating agents include those effective for preventing, retarding, arresting, and/or reversing skin wrinkles. Examples of suitable skin treating agents include, but are not limited to, alpha-hydroxy acids such as lactic acid and glycolic acid and beta-hydroxy acids. . .
- SUMM q) Humectants, Moisturizers, and Skin Conditioners
- SUMM Preferred compositions optionally comprise one or more humectants, moisturizers, or **skin** conditioners. A variety of these materials can be employed and each can be present at a level of from about. . .
- . products. More preferably, the compositions of the present SUMM invention are suitable for use as sunscreens to provide protection to human skin from the harmful effects of UV radiation which include, but are not limited to, sunburn and premature aging of the skin. The present invention therefore also further relates to methods of protecting human skin from the harmful effects of UV radiation. Such methods generally involve attenuating or reducing the amount of UV radiation which reaches the skin's surface. To protect the skin from UV radiation, a safe and effective (photoprotective) amount of the composition is topically applied to the skin. "Topical application" refers to application of the present compositions by spreading, spraying, etc. onto the surface of the skin. The exact amount applied may vary depending on the level of UV protection desired. From about 0.5 mg of composition per cm.sup.2 of skin to about 25 mg of composition per cm.sup.2 of skin are typically applied.
- CLM What is claimed is:

  18. A method for providing protection against the harmful effects of ultraviolet radiation to skin, said method comprising applying a safe and effective amount of the composition of claim 1 to skin.
- L3 ANSWER 5 OF 17 USPATFULL
- TI Pharmaceutical compositions and methods for improving wrinkles and other **skin** conditions

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PΙ

AΒ

This application relates to a pharmaceutical composition for the prevention and treatment of skin conditions in a patient having a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the skin, a primary antioxidant component in an amount sufficient to substantially inhibit the formation of collagenase and elastase, at least one amino acid component in an amount sufficient to assist in the thickening of the skin, and at least one transition metal component in an amount effective to bind collagen and elastic fibers and rebuild skin . In one preferred form, the composition further includes a catechin-based preparation, a glucosamine or a pharmaceutically acceptable salt or ester. . . a chondroitin or a pharmaceutically acceptable salt or ester thereof. In a more preferred form, the invention further includes a vitamin E source, a cysteine source, a vitamin B.sub.3 source, quercetin dihydrate, pyridoxal 5 phosphate-Co B.sub.6, a methionine source, and a vitamin A source. The invention further relates to a method for the prevention or treatment of skin conditions by administering the pharmaceutical composition in an amount therapeutically effective to modify the thickness of the skin to prevent or treat at least one skin condition.

SUMM . . . well as methods, to supplement collagen and elastic tissues and thicken the dermis for the treatment of wrinkles and other **skin** conditions.

Human skin is a composite material of the epidermis and the dermis. The topmost part of the epidermis is the stratum corneum. This layer is the stiffest layer of the skin, as well as the one most affected by the surrounding environment. Below the stratum corneum is the internal portion of. . . the dermis is the papillary dermis, which is made of relatively loose connective tissues that define the micro-relief of the skin. The reticular dermis, disposed beneath the papillary dermis, is tight, connective tissue that is spatially organized. The reticular dermis is. . .

The principal functions of the **skin** include protection, excretion, secretion, absorption, thermoregulation, pigmentogenesis, accumulation, sensory perception, and regulation of immunological processes. These functions are detrimentally affected by the structural changes in the **skin** due to aging and excessive sun exposure. The physiological changes associated with **skin** aging include impairment of the barrier function and decreased turnover of epidermal cells, for example. [Cerimele, D., et al., Br.. . .

The mechanical properties of the skin, such as elasticity, are controlled by the density and geometry of the network of collagen and elastic fiber tissue therein. Damaged collagen and elastin lose their contractile properties, resulting in skin wrinkling and skin surface roughness. As the skin ages or becomes unhealthy, it acquires sags, stretch marks, bumps, bruises or wrinkles, it roughens, and it has reduced ability to synthesize Vitamin D. Aged skin also becomes thinner and has a flattened dermoepidermal interface because of the alterations in collagen, elastin, and glycosaminoglycans. [Fenske, N. . . .

A variety of vitamins and minerals have in individually been administered to treat certain skin and other problems that occur when the patient has a deficiency of that vitamin or mineral.

Vitamin A, for example, assists in the treatment of acne and to facilitate wound healing; vitamin C (ascorbic acid) assists in the prevention of skin bruising and wound healing; vitamin E is an antioxidant; and copper assists in the treatment of elastic tissue defects. [Neldner, K. H., Amer. Acad. Derm. Annl. Mtg., Wash. D.C., Dec. 6, 1993]. Topical use of vitamin C is also believed to ward off sun

damage, reduce breakdown of connective tissues, and possibly promote collagen synthesis. [Dial, W., Medical World News, p. 12, March 1991]. Vitamin E is used topically as an anti-inflammatory agent, for enhancement of skin moisturization, for UV-ray protection of cells, and for retardation of premature skin aging.

- SUMM . . . metabolism of glycosaminoglycans under the influence of herbal and other anti-inflammatory agents has been examined by measuring glycosaminoglycans in the skin, liver, kidney, and spleen after administration of several compounds. [Reddy, G. K., et al., Biochem. Pharmacology, 38(20):3527-3534 (1989)].
- SUMM . . . a patient, various of the above ingredients have been combined to form pharmaceuticals designed to prevent and treat certain cellular, skin, and other conditions. For example, U.S. Pat. No. 3,773,930 discloses a low residue, dietary composition having at least one amino.
- SUMM U.S. Pat. No. 4,414,202 discloses a composition for the treatment of **skin** wounds with a buffered salt solution having a pH between 6 to 7.8 and administering a starch hydrolysate compound, and. . .
- SUMM U.S. Pat. No. 4,424,232 discloses a topical composition for the treatment of herpes simplex, cold sores, lesions, and other painful skin conditions including L-lysine, gibberellic acid, and urea in an inert carrier having water. The composition may also include L-ascorbic acid, . . .
- SUMM U.S. Pat. No. 5,198,465 discloses a composition for treating precursor deficiencies in the synthesis of collagen with proline, glycine, lysine, vitamin C, and one or more compounds selected from .alpha.-ketoglutaric acid, methionine, cysteine, cystine, valine, and pharmaceutically acceptable diluents and excipients.
- SUMM . . . complexes; an enzyme producer such as an amino acid like glutamic acid; an herbal antispasmodic substance like Valerian root; and vitamin C.
- SUMM U.S. Pat. No. 5,415,875 discloses a method of suppressing formation of lipid peroxide and removing peroxide by applying to the **skin** a decomposed product of shell membrane and tocopherol and derivatives. Lysine, proline, **Vitamin C**, for examples, are listed among a vast genus of optional additives.
- The above references, however, do not teach pharmaceutical compositions or methods for improving skin wrinkles along with other conditions, such as skin elasticity and softness. Thus, it is desired to find a pharmaceutical composition and a method for the prevention and treatment of wrinkles and other skin conditions. The present invention advantageously provides pharmaceutical compositions, as well as methods of treatment comprising the administration of such compositions, to repair skin for the prevention and treatment of wrinkles and other skin disorders.
- The present invention relates to a pharmaceutical composition for the prevention and treatment of **skin** conditions in a patient having a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the **skin**, a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase, at least one amino acid component in an amount sufficient to assist in the thickening of the **skin**, and at least one transition metal component in an amount effective to bind collagen and elastic fibers and rebuild **skin**
- In another preferred embodiment, the composition further includes a vitamin E source, a cysteine source, a vitamin B.sub.3 source, quercetin dihydrate, pyridoxal 5 phosphate-Co B.sub.6, a methionine source, and a vitamin A source. In a more preferred embodiment, the vitamin E is D-alpha tocopheryl acid succinate present

```
in about 1 to 15 weight percent, the vitamin B.
      sub.3 is niacinamide present in about 0.5 to 15 weight
      percent, the vitamin A is vitamin
      A palmitate present in about 0.1 to 5 weight percent, the
      cysteine is N-acetyl cysteine present in about 1 to 10.
      The invention further relates to a method for the prevention or
SUMM
      treatment of skin conditions, wherein the skin has a
      thickness of dermis and collagen, which includes administering the
      pharmaceutical composition above in an amount therapeutically effective
      to modify the thickness of the skin to prevent or treat at
      least one skin condition.
SUMM
      In one embodiment according to the invention, the skin
      condition treated is at least one of wrinkles, fine lines, thinning,
      reduced skin elasticity, reduced skin moisture,
      spider veins, senile purpura, sun damaged skin, aging
      skin, or rough skin. In another embodiment, the
      composition is administered orally. In a preferred embodiment, the
      composition is administered as a tablet or.
               conjunction with concurrent or subsequent treatment by at least
SUMM
      one additional pharmaceutical composition for the prevention or
      treatment of a skin condition.
SUMM
      A formulation for the reduction of wrinkles and the improvement of other
      skin conditions, such as increased skin elasticity and
      skin softness, has now been discovered. Moreover, the prevention
      or treatment of unhealthy skin, such as aged skin or
      skin overexposed to sunlight, may advantageously be accomplished
      by the administration of the pharmaceutical composition of the present
      invention to a. . . pharmaceutical composition includes the
      combination of a number of different components which interact to
      provide the desired improvements to the skin.
SUMM
      The advantageous pharmaceutical composition of the present invention
      prevents and improves skin conditions by using a sufficient
      amount of at least one sugar compound which is converted into
      glycosaminoglycans in the bloodstream,. . . supplementing collagen
      and elastic tissues. A thicker dermis desirably reduces the wrinkling
      and lines that occur when areas of the skin become thin.
      Various amino acids such as lysine, proline and cysteine assist in the
      thickening of the dermis, supplementing of collagen and elastic tissues
      and, consequently, reduction of wrinkles and other skin
      conditions. Additionally, antioxidants, such as vitamin
      c, inhibit collagenase and elastase, enzymes that break down
      collagen and elastic tissues. These antioxidants assist in the
      prevention of additional wrinkles and facilitate the healing of
      skin tissues. Finally, transition metal components are included
      to bind collagen fibers and inhibit elastase, an enzyme that also breaks
SUMM
      The pharmaceutical composition includes a primary antioxidant, which
      typically is a vitamin C source and preferably is
      ascorbic acid, or a pharmaceutically acceptable salt or ester thereof,
      and more preferably is ascorbyl palmitate,. . . or mixtures thereof.
      When oral formulations of the pharmaceutical composition are used, it is
      preferred that a non-acidic form of vitamin C be
      used to reduce the stomach irritation that may occur when using an
      acidic form. The vitamin C source is present in the
      pharmaceutical composition in about 5 to 50 weight percent, preferably
      about 7 to 40 weight percent, and more preferably about 10 to 25 weight
      percent. A unit dose of this primary vitamin C
      source is typically about 40 mg to 400 mg, preferably about 60 mg to 300
      mg, and more preferably about 80 to 150 mg. Vitamin C
      is also approved by the FDA and has wide consumer acceptance, so that it
      can be used in amounts as.
SUMM
      The pharmaceutical composition also includes at least one amino acid to
```

assist in thickening the skin. Preferably two or more amino acids are used in combination. Either the L- or D- forms of amino acids . or more transition metal compounds are included in an amount effective to bind collagen and elastic tissue to rebuild the skin. Certain transition metal compounds inhibit the elastase enzyme to inhibit collagen and elastic tissue breakdown. Preferred transition metals include zinc,. . . assist in binding collagen and elastic fibers, which both assists in the prevention of wrinkles and the rebuilding of wrinkled skin. The zinc component may be any zinc compound or pharmaceutically acceptable salt thereof, but more preferably is a zinc complexed. . or pharmaceutically acceptable salt thereof, but more preferably is a manganese component which is at least partially complexed with a vitamin C source, and most preferably is manganese ascorbate or manganese ascorbic acid, wherein the manganese is typically present in about 5 to 20 weight percent of the complex. When complexed with vitamin C, this vitamin C source may be included in the overall percentage of vitamin C in the pharmaceutical composition. The manganese component is present in about 1 to 10 weight percent, more preferably about 2. The catechin-based preparation, similar to vitamin C , inhibits elastase and collagenase, which is another enzyme that attacks elastic tissue and collagen. The catechin-based preparation is preferably a. . . . 90 weight percent of the salt. The glucosamine content of this component contributes to the formation of glycosoaminoglycans in the skin. The chondroitin component preferably is present as a sulfate or succinate, and more preferably is chondroitin sulfate, wherein the chondroitin. In a more preferred form, several optional additives are included in the pharmaceutical composition, such as a vitamin E source, a vitamin B.sub.3 source, quercetin powder, pyridoxal 5 phosphate-Co B.sub.6, and a vitamin A source. The vitamin E preferably is a sulfate or succinate vitamin E complex, and more preferably is D-alpha tocopheryl acid succinate. The vitamin E source is present in about 1 to 15 weight percent, preferably about 2 to 12 weight percent, and more preferably. 10 weight percent of the composition. In any event, no more than 1,500 IU should be ingested per day, as Vitamin E becomes toxic at higher doses. The vitamin B. sub.3 source preferably is niacinamide, and the source is present in about 0.5 to 15 weight percent, preferably about 1 to 12 weight percent, and more preferably about 1.5 to 10 weight percent of the composition. The vitamin A source preferably is vitamin A palmitate, and the source is present in about 0.1 to 5 weight percent, preferably 0.2 to 3 weight percent, and more preferably 0.3 to 1 weight percent of the composition. In the more preferred form, the amount of vitamin A dosage is about 500,000 IU/gram per unit dose. Vitamin A is toxic at high levels, such that no more than 400,000 IU should be cumulatively ingested per day for greater. . . . amount" means that amount of the pharmaceutical composition that provides a therapeutic benefit in the treatment, prevention, or

DETD

conditions.

SUMM

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Weight Chemical or Percent Amount Scientific Name

management of skin wrinkles and other skin

Ingredient (% w/w)	(mg)	(if different)	
N-Acetylglucosamine		<del></del>	
17.1	140	N-Acetyl D- Glucosamine	
Vitamin C (81.2% 15	123.2		
Ascorbic Acid)			
L-Lysine (80%) 12.2	100	L-Lysine hydrochloride	
L-Proline 11	90	nyarosmiorias	
D-Glucosamine Sulfate	50.0		
6.5 (75%)	53.3		
Chondroitin Sulfate			
6.1	50		
(80%) Vitamin E Succinate	•		
4.3	39.7	Dalpha. tocopheryl acid succinate	
Zinc monomethionine		acid succinate	
3.7	30	Zinc DL-	
(20%) N-Acetyl Cysteine		methionine	
3.7	30	•	*
Manganese Ascorbate	22 1		
2.8 (13% Mn)	23.1		
Vitamin B.sub.3			
2.4 Niacinamide	20	Niacinamide	
Quercetin Powder			
2.4	20	Quercetin dihydrate	
Grape Seed Extract		dinydrace	
0.9	7.5	Proanthocyanidin	
Pyridoxal 5 0.6 Phosphate-Co B.sub.6	5	P-5-P monohydrate	
Selenomethionine			
0.5 (0.5%)	4	L- selenomethionine	
Vitamin A Palmitate			
0.5	4		
(500,000 IU/GR) Copper Sebacate (14%)			
0.4	2.9		
Red beet root powder 6.1	50	Beta vulgaris	
		rubra	
Stearic acid 1.5 Sorbitol 1.3	12		
DETD 73 fema		cts to determine the effects on the elasticity,	
firmness, and pr	resence of	f fine lines and wrinkles of the <b>skin.</b> period was used prior to initiation of the	
study, where sub	ojects we	re instructed to discontinue use	
		fine lines, and wrinkles were	
		o replicas of the periorbital area (crow's feet) eplicas, were illuminated at a precisely defined	
angle of 35.deg	ree. to c	reate shadows for analysis by shades of gray.	
		efined by the: (a) number of wrinkles; es; (c) total length of wrinkles; (d)	
(,			

- DETD . . . is a function of the length of treatment as indicated above.

  This strongly suggests the treatment has imparted an improved skin infrastructure by beneficially affecting the dermis of the skin.
- The Ballistometer is an instrument designed to evaluate in vivo, in a non-invasive manner, the viscoelastic properties of the skin.

  It analyzes the bounce pattern displayed by a probe that is allowed to impact on the skin. The kinetic energy of the probe striking the skin is stored by the elastic components of the skin and released back to make the probe rebound to a lower height. The height to which the probe will rebound depends upon the amount of stored energy lost in shear viscosity within the skin
- DETD The capacity of the **skin** to absorb mechanical energy may thus be measured. Although it is unclear exactly which layer, or layers, of the **skin** are responsible, the mechanical properties of the dermis/epidermis layers are controlled by the density and geometry of the network of. . .
- DETD . . . less of the energy of the striking probe was restored, thus, a greater amount of energy was dissipated in the **skin**. This suggests the **skin** became softer and more yielding during the test period.
- The Cutometer is a commercially available instrument (Courage & Khazaka, Germany) designed to measure the mechanical properties of the skin in a non-invasive manner. It measures the vertical deformation of the skin's surface when pulled by vacuum suction (500 mm Hg) through the small aperture (2 mm) of a probe and the depth of penetration of the skin into the probe optically with an accuracy of 0.01 mm. The probe is attached to a computer, which completely controls probe operation and plots skin deformation as a function of time. From this curve, a number of variables can be extrapolated to estimate the elastic, viscoelastic, and purely viscous behavior of the skin.
- DETD . . . final distension (U.sub.f), measured at 10 seconds; and (d) immediate retraction (U.sub.r). The deformation parameters are extrinsic parameters dependent on **skin** thickness, and a variety of biologically important ratios were calculated: (a) U.sub.r /U.sub.f, a measure of net elasticity of the **skin**; (b) U.sub.r /U.sub.e, the biological elasticity, or measurement of the ability of the **skin** to regain its initial configuration after deformation; and (c) U.sub.v /U.sub.e, the viscoelastic to elastic ratio, where an increase in. . .
- DETD . . . distension (U.sub.v) decreased a significant 16 percent (p<0.04) after 5 weeks of treatment. This parameter reflects viscoelastic properties of the  ${\bf skin}$  and, thus, the behavior of the dermis. After 5 weeks, there were no statistically significant changes in U.sub.e, the immediate. . .
- The general appearance of soft, smooth **skin** depends largely on the presence of an adequate amount of water in the stratum corneum. The Corneometer is a commercially available instrument (Courage & Khazaka, Germany) to measure the changes in capacitance of the **skin** resulting from changes in the degree of hydration. It is particularly sensitive to low levels of hydration, and uses measurements of arbitrary units of **skin** hydration (H) to express capacitance.
- DETD . . . moisturizing agents and humectants. Thus, the measurements with the Ballistometer and Cutometer indicate changes occurred in deeper layers of the **skin**, rather than the superficial stratum corneum. Table IV shows no significant changes in the hydration of the stratum corneum following. . .

DETD TABLE IV

Skin Hydration (H) Mid-Baseline

Final-Baseline

Control

Treated Control Treated

Avera	age	-5	-7	 -8	-4
Stand	dard	Deviation			
		6	7	5	7
p val	lue	p <.	•		

CLM What is claimed is:

- 1. An orally administered pharmaceutical composition for the prevention and treatment of **skin** conditions in a patient comprising: a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the **skin**; a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase; at least one amino acid component in an amount sufficient to assist in the thickening of the **skin**; and at least one transition metal component in an amount effective to bind collagen and elastic fibers and thicken **skin**
- 7. The pharmaceutical composition of claim 1, further comprising a vitamin E source, a cysteine source, a vitamin B.sub.3 source, quercetin dihydrate, pyridoxal 5 phosphate-Co B.sub.6, a methionine source, and a vitamin A source.
- 8. The pharmaceutical composition of claim 7, wherein the vitamin E is D-alpha tocopheryl acid succinate present in about 1 to 15 weight percent, the vitamin B. sub.3 is niacinamide present in about 0.5 to 15 weight percent, the vitamin A is vitamin A palmitate present in about 0.1 to 5 weight percent, the cysteine is N-acetyl cysteine present in about 1 to 10. 9. A method for the prevention or treatment of skin conditions, wherein the skin has a thickness of dermis and collagen, which comprises administering to a patient: a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the skin; a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase; at least one amino acid component in an amount sufficient to assist in the thickening of the skin; and at least one transition metal component in an amount effective to bind collagen and elastic fibers and thicken skin, so as to modify the thickness of the skin to prevent or treat at least one skin condition.
- 10. The method of claim 9, wherein the skin condition prevented or treated is at least one of wrinkles or the appearance thereof, fine lines or the appearance thereof, thinning, reduced skin elasticity, reduced skin moisture, spider veins, senile purpura, sun damaged skin, aging skin or rough skin.
- . conjunction with concurrent or subsequent treatment by at least one additional pharmaceutical composition for the prevention or treatment of a **skin** condition.
- 13. A method for the prevention or treatment of **skin** conditions, wherein the **skin** has a thickness of dermis and collagen, which comprises administering to a patient: a sugar compound that is converted to a glycosaminoglycan in the patient in an amount

sufficient to thicken the skin; a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase; at least one amino acid component in an amount sufficient to assist in the thickening of the skin; at least one transition metal component in an amount effective to bind collagen and elastic fibers and thicken skin; and a catechin-based component present in an amount sufficient to inhibit the presence of an anti-collagen enzyme in the skin, so as to modify the thickness of the skin to prevent or treat at least one skin condition.

14. An pharmaceutical composition for the prevention and treatment of skin conditions in a patient consisting essentially of: a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the skin; a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase; at least one amino acid component in an amount sufficient to assist in the thickening of the skin; and at least one transition metal component in an amount effective to bind collagen and elastic fibers and thicken skin.

ANSWER 6 OF 17 USPATFULL

L3

19991026

ΡI US 5972316 It is well known that exposure to sunlight can pose a number of hazards SUMM to the skin. These damaging effects may result not only from sunbathing but also from the sunlight exposure associated with daily outdoor activities.. . . a wavelength of from about 290 nm to about 320 nm. Over the long term, however, malignant changes in the skin surface often occur. Numerous epideminologic studies demonstrate a strong relationship between sunlight exposure and human skin cancer. Another long term hazard of ultraviolet radiation is premature aging of the skin, which is primarily caused by UVA radiation having a wavelength of from about 320 nm to about 400 nm. This condition is characterized by wrinkling and pigment changes of the skin, along with other physical changes such as cracking, telangiectasis, solar dermatoses, ecchymoses, and loss of elasticity.

The adverse effects associated. . . . care products" refer to health and cosmetic beauty aid products SUMM generally recognized as being formulated for beautifying and grooming the skin and hair. For example, personal care products include sunscreen products (e.g., lotions, skin creams, etc.), cosmetics, toiletries, and over-the-counter pharmaceutical products intended for topical usage.

. . are efficient at absorbing UV radiation in the 290 nm to 320 nm SUMM UVB region such that sunburn of the skin is prevented. They are less efficient when it comes to absorbing light which falls in the 320 nm to 400 nm UVA region, which leaves the skin vulnerable to premature skin aging. This deficiency is due in part to the limited number of UVA absorbing sunscreen actives which are both commercially.

. . . there is a need for photostabilized compositions suitable for SUMM providing protection against the harmful effects of UV radiation to human skin. In particular, in the personal care industry, a need remains for sunscreen products having excellent photostability, efficiency, and which provide.

. . . and most preferably from about 2:1 to about 1:1. The present SUMM invention also relates to methods for providing protection to skin from the harmful effects of UV radiation by topical application of such compositions. Furthermore, the present invention relates to methods.

. . . compositions of the present invention are useful for providing protection against the harmful effects of ultraviolet radiation,

SUMM

especially to human skin. The essential components of these compositions are described below. Also included is a nonexclusive description of various optional and preferred. . . against erythema. The SPF is defined as the ratio of the ultraviolet energy required to produce minimal erythema on protected skin to that required to produce the same minimal erythema on unprotected skin in the same individual. See Federal Register, 43, No. 166, pp. 38206-38269, Aug. 25, 1978). . . . use application. For example, carriers of the present invention include, but are not limited to, those suitable for application to skin, hair, nails, animal skin, fur, automobiles, fabrics, marine vehicles, as well as those suitable for incorporation into plastics, metals, etc. Preferably, the carriers of the present invention are suitable for application to skin (e.g., sunscreens, creams, milks, lotions, masks, serums, etc.); hair and fur (e.g., shampoos, hair setting or treatment gels or lotions,. lacquers or lotions, etc,); and nails (e.g., polishes, treatments, etc.). In preferred embodiments, the carrier is suitable for application to skin which means that the carrier and its components are suitable for use in contact with skin, hair, fur, and nails without undue toxicity, incompatibility, instability, allergic response, and the like within the scope of sound medical. . . and can include one or more compatible liquid or solid filler diluents or vehicles which are suitable for application to skin, hair, fur, and nails. The exact amount of carrier will depend upon the level of the UVA-absorbing dibenzoylmethane sunscreen active,. . . . . etc.), hair care and styling products (e.g., shampoos, conditioners, gels, mousses, sprays, etc.), topical animal care items (e.g., shampoos, conditioners, skin treatments, etc.). Any additional components required to formulate such products vary with product type and can be routinely chosen by. If compositions of the present invention are formulated as an aerosol and applied to the skin as a spray-on product, a propellant is added to the composition. Examples of suitable propellants include chlorofluorinated lower molecular weight. In a preferred embodiment, where the composition is to be in contact with human skin, the optional components should be suitable for application to skin, that is, when incorporated into the composition they are suitable for use in contact with human skin without undue toxicity, incompatibility, instability, allergic response, and the like within the scope of sound medical judgment. The CTFA Cosmetic Ingredient Handbook, Second Edition (1992) describes a wide variety of nonlimiting cosmetic and pharmaceutical ingredients commonly used in the skin care industry, which are suitable for use in the compositions of the present invention. Examples of these ingredient classes include: abrasives, absorbents, aesthetic components such as fragrances, pigments, colorings/colorants, essential oils, skin sensates, astringents, etc. (e.g., clove oil, menthol, camphor, eucalyptus oil, eugenol, menthyl lactate, witch hazel distillate), anti-acne agents, anti-caking agents,. . . and substantivity of the composition (e.g., copolymer of eicosene and vinyl pyrrolidone), opacifying agents, pH adjusters, propellants, reducing agents, sequestrants, skin bleaching and lightening agents (e.g., hydroquinone, kojic acid, ascorbic acid, magnesium ascorbyl phosphate, ascorbyl glucosamine), skin-conditioning agents (e.g., humectants, including miscellaneous and occlusive), skin soothing and/or healing agents (e.g., panthenol and derivatives (e.g., ethyl panthenol), aloe vera, pantothenic acid and its derivatives, allantoin, bisabolol, and dipotassium glycyrrhizinate), skin treating agents, thickeners, and vitamins and derivatives thereof. . . . such optional components. Preferred compositions optionally contain one or more materials selected from UVB sunscreen actives,

SUMM

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anti-acne actives, vitamin compounds, skin treating agents, humectants, moisturizers, skin conditioners, thickening agents, structuring agents, and emulsifiers. SUMM These vitamin compounds may be in either natural or synthetic form. Suitable vitamin compounds include, but are not limited to, Vitamin A (e.g., beta carotene, retinoic acid, retinol, retinoids, retinyl palmitate, retinyl proprionate, etc.), Vitamin B (e.g., niacin, niacinamide, riboflavin, pantothenic acid, etc.), Vitamin C (e.g., ascorbic acid, etc.), Vitamin D (e.g., ergosterol, ergocalciferol, cholecalciferol, etc.), Vitamin E (e.g., tocopherol acetate, etc.), and Vitamin K (e.g., phytonadione, menadione, phthiocol, etc.) compounds. SUMM In particular, the compositions of the present invention may comprise a safe and effective amount of a vitamin B.sub .3 compound. Vitamin B.sub. 3 compounds are particularly useful for regulating skin condition as described in co-pending U.S. application Ser. No. 08/834,010, filed Apr. 11, 1997 (corresponding to international publication WO 97/39733. . and still more preferably from about 1%to about 5%, most preferably from about 2% to about 5%, of the vitamin B.sub.3 compound. SUMM As used herein, "vitamin B.sub.3 compound" means a compound having the formula: ##STR12## wherein R is --CONH.sub.2 (i.e., niacinamide), --COOH (i.e., nicotinic acid) or SUMM Exemplary derivatives of the foregoing vitamin B. sub. 3 compounds include nicotinic acid esters, including non-vasodilating esters of nicotinic acid, nicotinyl amino acids, nicotinyl alcohol esters of carboxylic acids,. . SUMM Examples of suitable vitamin B.sub. 3 compounds are well known in the art and are commercially available from a number of sources, e.g., the Sigma Chemical. SUMM d) Skin Treating Agent SUMM The compositions of the present invention may contain one or more skin treating agents. Suitable skin treating agents include those effective for preventing, retarding, arresting, and/or reversing skin wrinkles. Examples of suitable skin treating agents include, but are not limited to, alpha-hydroxy acids such as lactic acid and glycolic acid and beta-hydroxy acids. SUMM g) Humectants, Moisturizers, and Skin Conditioners SUMM Preferred compositions optionally comprise one or more humectants, moisturizers, or skin conditioners. A variety of these materials can be employed and each can be present at a level of from SUMM . products. More preferably, the compositions of the present invention are suitable for use as sunscreens to provide protection to human skin from the harmful effects of UV radiation which include, but are not limited to, sunburn and premature aging of the skin. The present invention therefore also further relates to methods of protecting human skin from the harmful effects of UV radiation. Such methods generally involve attenuating or reducing the amount of UV radiation which reaches the skin's surface. To protect the skin from UV radiation, a safe and effective (photoprotective) amount of the composition is topically applied to the skin. "Topical application" refers to application of the present compositions by spreading, spraying, etc. onto the surface of the skin. The exact amount applied may vary depending on the level of UV protection desired. From about 0.5 mg of composition per cm.súp.2 of skin to about 25 mg of composition per cm.sup.2 of skin are typically applied. CLM What is claimed is:

. effects of ultraviolet radiation, said method comprising applying a safe and effective amount of the composition of claim 1 to  ${f skin}$ 

L3 ANSWER 7 OF 17 USPATFULL

SUMM ·

PI US 5968485 19991019

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SUMM It is well known that exposure to sunlight can pose a number of hazards to the skin. These damaging effects may result not only from sunbathing but also from the sunlight exposure associated with daily outdoor activities... a wavelength of from about 290 nm to about 320 nm. Over the long term, however, malignant changes in the skin surface often occur. Numerous epideminologic studies demonstrate a strong relationship between sunlight exposure and human skin cancer. Another long term hazard of ultraviolet radiation is premature aging of the skin, which is primarily caused by UVA radiation having a wavelength of from about 320 nm to about 400 nm. This condition is characterized by wrinkling and pigment changes of the skin, along with other physical changes such as cracking, telangiectasis, solar dermatoses, ecchymoses, and loss of elasticity. The adverse effects associated. . .

SUMM . . . care products" refer to health and cosmetic beauty aid products generally recognized as being formulated for beautifying and grooming the **skin** and hair. For example, personal care products include sunscreen products (e.g., lotions, **skin** creams, etc.), cosmetics, toiletries, and over-the-counter pharmaceutical products intended for topical usage.

SUMM . . . are efficient at absorbing UV radiation in the 290 nm to 320 nm UVB region such that sunburn of the **skin** is prevented. They are less efficient when it comes to absorbing light which falls in the 320 nm to 400 nm UVA region, which leaves the **skin** vulnerable to premature **skin** aging. This deficiency is due in part to the limited number of UVA absorbing sunscreen actives which are both commercially. . .

SUMM . . . there is a need for photostabilized compositions suitable for providing protection against the harmful effects of UV radiation to human **skin**. In particular, in the personal care industry, a need remains for sunscreen products having excellent photostability, efficiency, and which provide. . .

SUMM . . . and most preferably from about 2:1 to about 1:1. The present invention also relates to methods for providing protection to skin from the harmful effects of UV radiation by topical application of such compositions. Furthermore, the present invention relates to methods. . .

SUMM . . . compositions of the present invention are useful for providing protection against the harmful effects of ultraviolet radiation, especially to human **skin**. The essential components of these compositions are described below. Also included is a nonexclusive description of various optional and preferred. . .

. . . against erythema. The SPF is defined as the ratio of the ultraviolet energy required to produce minimal erythema on protected skin to that required to produce the same minimal erythema on unprotected skin in the same individual. See Federal Register, 43, No. 166, pp. 38206-38269, Aug. 25, 1978).

SUMM . . . use application. For example, carriers of the present invention include, but are not limited to, those suitable for application to skin, hair, nails, animal skin, fur, automobiles, fabrics, marine vehicles, as well as those suitable for incorporation into plastics, metals, etc. Preferably, the carriers of the present invention are suitable for application to skin (e.g., sunscreens, creams, milks, lotions, masks, serums, etc.); hair and fur (e.g., shampoos, hair setting or treatment gels or lotions, . .

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lacquers or lotions, etc,); and nails (e.g., polishes, treatments,
etc.). In preferred embodiments, the carrier is suitable for application
to skin which means that the carrier and its components are
suitable for use in contact with skin, hair, fur, and nails
without undue toxicity, incompatibility, instability, allergic response,
and the like within the scope of sound medical. . . and can include
one or more compatible liquid or solid filler diluents or vehicles which
are suitable for application to skin, hair, fur, and nails.
The exact amount of carrier will depend upon the level of the
UVA-absorbing dibenzoylmethane sunscreen active,.
     . etc.), hair care and styling products (e.g., shampoos,
conditioners, gels, mousses, sprays, etc.), topical animal care items
(e.g., shampoos, conditioners, skin treatments, etc.). Any
additional components required to formulate such products vary with
product type and can be routinely chosen by.
If compositions of the present invention are formulated as an aerosol
and applied to the skin as a spray-on product, a propellant is
added to the composition. Examples of suitable propellants include
chlorofluorinated lower molecular weight.
In a preferred embodiment, where the composition is to be in contact
with human skin, the optional components should be suitable
for application to skin, that is, when incorporated into the
composition they are suitable for use in contact with human skin
without undue toxicity, incompatibility, instability, allergic response,
and the like within the scope of sound medical judgment. The CTFA
Cosmetic Ingredient Handbook, Second Edition (1992) describes a wide
variety of nonlimiting, cosmetic and pharmaceutical ingredients commonly
used in the skin care industry, which are suitable for use in
the compositions of the present invention. Examples of these ingredient
classes include: abrasives, absorbents, aesthetic components such as
fragrances, pigments, colorings colorants, essential oils, skin
sensates, astringents, etc. (e.g., clove oil, menthol, camphor,
eucalyptus oil, eugenol, menthyl lactate, witch hazel distillate),
anti-acne agents, anti-caking agents,. . . and substantivity of the
composition (e.g., copolymer of eicosene and vinyl pyrrolidone),
opacifying agents, pH adjusters, propellants, reducing agents,
sequestrants, skin bleaching and lightening agents (e.g.,
hydroquinone, kojic acid, ascorbic acid, magnesium ascorbyl phosphate,
ascorbyl glucosamine), skin-conditioning agents (e.g.,
humectants, including miscellaneous and occlusive), skin.
soothing and/or healing agent (e.g., panthenol and derivatives (e.g.,
ethyl panthenol), aloe vera, pantothenic acid and its derivatives,
allantoin, bisabolol, and dipotassium glycyrrhizinate), skin
treating agents, thickeners, and vitamins and derivatives thereof.
     . such optional components. Preferred compositions optionally
contain one or more materials selected from UVB sunscreen actives,
anti-acne actives, vitamin compounds, skin treating agents,
humectants, moisturizers, skin conditioners, thickening
agents, structuring agents, and emulsifiers.
  . . These vitamin compounds may be in either natural or synthetic
form. Suitable vitamin compounds include, but are not limited to,
Vitamin A (e.g., beta carotene, retinoic acid,
retinol, retinoids, retinyl palmitate, retinyl proprionate, etc.),
Vitamin B (e.g., niacin, niacinamide, riboflavin, pantothenic acid,
etc.), Vitamin C (e.g., ascorbic acid, etc.),
Vitamin D (e.g., ergosterol, ergocalciferol,
cholecalciferol, etc.), Vitamin E (e.g., tocopherol
acetate, etc), and Vitamin K (e.g., phytonadione, menadione, phthiocol,
etc.) compounds.
In particular, the compositions of the present invention may comprise a
safe and effective amount of a vitamin B. sub
.3 compound. Vitamin B.sub.
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SUMM

SUMM

SUMM

SUMM

SUMM

SUMM

3 compounds are particularly useful for regulating skin condition as described in co-pending U.S. application Ser. No. 08/834,010, filed Apr. 11, 1997 (corresponding to international publication WO 97/39733. . . and still more preferably from about 1% to about 5%, most preferably from about 2% to about 5%, of the vitamin B.sub.3 compound.

SUMM As used herein, "vitamin B.sub.3 compound" means a compound having the formula: ##STR7## wherein R is --CONH.sub.2 (i.e., niacinamide), --COOH (i.e., nicotinic acid) or --CH.sub.2. . .

SUMM Exemplary derivatives of the foregoing vitamin B.

sub.3 compounds include nicotinic acid esters,
including non-vasodilating esters of nicotinic acid, nicotinyl amino
acids, nicotinyl alcohol esters of carboxylic acids,. . .

SUMM Examples of suitable **vitamin B.sub.**3 compounds are well known in the art and are commercially available from a number of sources, e.g., the Sigma Chemical. .

SUMM d) Skin Treating Agent

SUMM The compositions of the present invention may contain one or more skin treating agents. Suitable skin treating agents include those effective for preventing, retarding, arresting, and/or reversing skin wrinkles. Examples of suitable skin treating agents include, but are not limited to, alpha-hydroxy acids such as lactic acid and glycolic acid and beta-hydroxy acids. . .

SUMM g) Humectants, Moisturizers, and **Skin** Conditioners
SUMM Preferred compositions optionally comprise one or more humectants,
moisturizers, or **skin** conditioners. A variety of these
materials can be employed and each can be present at a level of from

SUMM . . . products. More preferably, the compositions of the present invention are suitable for use as sunscreens to provide protection to human skin from the harmful effects of UV radiation which include, but are not limited to, sunburn and premature aging of the skin. The present invention therefore also further relates to methods of protecting human skin from the harmful effects of UV radiation. Such methods generally involve attenuating or reducing the amount of UV radiation which reaches the skin's surface. To protect the skin from UV radiation, a safe and effective (photoprotective) amount of the composition is topically applied to the skin. "Topical application" refers to application of the present compositions by spreading, spraying, etc. onto the surface of the skin. The exact amount applied may vary depending on the level of UV protection desired. From about 0.5 mg of composition per cm.sup.2 of skin to about 25 mg of composition per cm.sup.2 of skin are typically applied.

CLM What is claimed is:

18. A method for protecting skin from the harmful effects of ultraviolet radiation, said method comprising applying a safe and effective amount of the composition of claim 1 to skin.

L3 ANSWER 8 OF 17 USPATFULL

PI US 5962517 19991005 <--

AB . . . blemishes associated with acne. The invention also relates to pharmaceutical compositions having, in addition to the acne reduction component, a skin cell conditioning component in an amount sufficient to properly regulate the keratin and sebum production of the skin cells, thereby inhibiting the appearance of acne. In a preferred form, the skin cell conditioning component is a chromium component. In another preferred form, the composition further includes at least one of a vitamin C source, burdock root, yellow dock root, horsetail extract, a catechin-based composition,

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a vitamin B.sub.1 source, a vitamin B.sub.2 source, a vitamin
      B.sub.3 source, a vitamin B.sub.5 source,
       and a vitamin E source. In a more preferred form,
       the invention also includes at least one amino acid component, a
      magnesium component, a. . . amount therapeutically effective in
       reducing the incidence of acne and methods for additionally inhibiting
       the appearance of acne by conditioning skin cells.
      This invention relates to pharmaceutical compositions for treating acne
SUMM
      and conditioning the skin cells in patients. The invention
       further relates to methods of treating acne and conditioning
       skin cells by administering the pharmaceutical compositions to
       the patient.
SUMM
      The mammalian skin, in particular, human skin, is a
      multifunctional organ. Not only does the skin provide an
       external covering to protect the body, but it also performs several
       specialized functions, such as breathing, perspiring, sensory.
      production. [D. Mowery, The Scientific Validation of Herbal Medicine,
      248 (1986)]. Oil production, essential to the protective features of the
      skin, works when an oily substance known as sebum is released
      from the sebaceous glands, which are large glands located at the base of
      a hair follicle. This permits the skin to moisturize and
      waterproof itself, thereby protecting itself from the environment. [J.
      Whitaker, Dr. Whitaker's Guide to Natural Healing, 141,. . .
SUMM
       . . . insoluble protein that is the primary constituent of the hair
      and the epidermis. Together, the sebum and keratin block a skin
      pore, resulting in a comedone, also known as a blackhead. Bacteria
      proliferates in clogged pores, and the body typically responds. .
       . . the gland, mixes with dead cells, and eventually ruptures the
SUMM
      follicle wall, which typically forms a deep cyst under the skin
       . Scarring often results from these deep cysts. [Roche Laboratories
      Inc., Important Information Concerning Your Treatment with Accutane, 6th
      ed., (1996)]..
SUMM
       . . . benzoyl peroxide, erythromycin, clindamycin, or tetracycline
      are commonly used to control the bacteria. These methods often lead to
      overly dry skin, and relapse is common after treatment has
      ended. [Id.].
SUMM
      Vitamins and herbs often provide more promising results with regard to
      acne. Vitamin A has proven to be highly effective in
      treating acne. Since the early seventies, topical retinoic acid or
      tretinoin, both derivatives of vitamin A, have been
      used to treat acne topically. [Id.]. These topical agents work by
      normalizing the skin's production of keratin and the sebaceous
      glands production of sebum, thereby preventing obstruction of the
      follicle. Although highly effective, the.
SUMM
      A systemic vitamin A derivative for the treatment of
      nodular acne, known as isotretinoin, is commercially available under the
      name ACCUTANE.RTM., from Roche Laboratories.
SUMM
       . . . because of its ability to aid in wound healing, immune
      response, inflammation control, tissue regeneration, and more effective
      utilization of vitamin A. Certain studies have shown
      that zinc produces results similar to tetracycline in the treatment of
      superficial acne, but far superior. . . acne. [J. Whitaker, Dr.
      Whitaker's Guide to Natural Healing, 142 (1995)]. Also, certain
      nutrients, such as vitamin B.sub.6, selenium, and vitamin
      E, are thought necessary to healthy skin and,
      therefore, control acne. [Id.].
SUMM
       . . . 158 (1988)]. Additionally, herbs possessing antibiotic
      properties, such as burdock root and horsetail, may individually aid in
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the treatment of skin blemishes, such as acne. [D. Mowery, The

. . . company, has been used in conjunction with a cleanser and topical cream to treat acne. The nutritional supplement contains zinc,

Scientific Validation of Herbal Medicine, 32-33 (1986)].

SUMM

vitamin A, vitamin C, and other natural elements that are believed to nourish the skin. Also, it is suggested that high doses of vitamin A are not needed in AKNE-ZYME.TM. as long as other nutritional factors such as zinc, vitamin B.sub.6, selenium, and vitamin E are incorporated into the acne treatment. [J. Whitaker, Dr. Whitaker's Guide to Natural Healing, 141-142 (1995)].

. . . that the herbal extract be used in conjunction with supplements

SUMM . . . that the herbal extract be used in conjunction with supplements of one or more of the following nutrients and minerals: vitamin A, vitamin B.sub.1, vitamin B.sub.2, vitamin B.sub.6, vitamin B complex, vitamin C, vitamin D, vitamin E, niacinamide, pantothenic acid,

para-aminobenzoic acid, biotin, choline, inositol, folic acid, zinc, calcium, magnesium, and potassium. The reference further notes the.

SUMM . . . the above references disclose methods of treating acne, the treatments often involve adverse side effects, such as overdrying of the skin. Furthermore, the above treatments simply address the acne and fail to condition the skin cells to assist in the treatment and to reduce further incidences of acne. Thus, it is desired to find pharmaceutical compositions and methods for treating acne by administering the pharmaceutical compositions and conditioning the skin to inhibit further acne outbreaks without the adverse side effects present in many conventional acne treatments. The present invention, through a blend of herbal extracts and nutritional supplements, advantageously treats acne without adverse side effects, and conditions skin cells to reduce the likelihood of further acne.

SUMM . . . comprising an acne reduction component in an amount sufficient to reduce the redness and blemishes associated with acne and a skin cell conditioning component in an amount sufficient to properly regulate the keratin and sebum production of the skin cells to inhibit the appearance of acne.

SUMM The **skin** cell conditioning component comprises a transition metal complex with an organic compound. In a preferred embodiment, the transition metal is. . .

The acne reduction component is a vitamin A source, a carotenoid component, a vitamin B.sub.6 source, and a zinc component. In a preferred embodiment, the vitamin A source is vitamin A complexed with an acetate or palmitate, the carotenoid component is beta-carotene, the vitamin B.sub.6 source is a pyridoxine, and the zinc component is zinc complexed with ascorbic acid or ascorbate. In a more preferred embodiment, the vitamin A source is vitamin A palmitate present in about 0.005 to 5 weight percent, beta-carotene is present in about 0.1 to 10 weight percent, the. . .

Another embodiment of the pharmaceutical composition also has at least SUMM one of a vitamin C source, burdock root, yellow dock root, horsetail extract, a catechin-based composition, a vitamin B.sub.1 source, a vitamin B.sub.2 source, a vitamin B. sub.3 source, a vitamin B.sub.5 source, and a vitamin E source, all in an amount sufficient to facilitate maintenance of skin cells. In a preferred embodiment, the vitamin C source is ascorbic acid or ascorbate, the catechin-based composition is a proanthanol or proanthocyanidin, the vitamin B.sub.l source is thiamin, the vitamin B. sub. 2 source is riboflavin, the vitamin B. sub.3 source is niacinamide, the vitamin B.sub.5 source is pantothenic acid, and the vitamin E source is a sulfate or succinate vitamin E complex. In a more preferred embodiment, the vitamin C source is calcium ascorbate present in about 1 to 30 weight percent, the burdock

root is present in about 1. . . in about 0.05 to 5 weight percent, the thiamin is present in about 0.05 to 5 weight percent and the  ${\bf vitamin}~{\bf E}$  source is  ${\bf vitamin}~{\bf E}$ 

succinate present in about 1 to 30 weight percent.

SUMM . . . one amino acid component, a magnesium component, a selenium component, and biotin in an amount sufficient to facilitate repair of skin damaged by acne. In a preferred embodiment, the amino acid component is L-lysine and L-proline, the magnesium component is magnesium. . .

SUMM . . . effective to reduce the redness and blemishes associated with acne. In addition, the invention relates to a method for conditioning skin cells in a treatment for acne, by administering these pharmaceutical compositions in an amount therapeutically effective to condition the skin to assist in reducing the redness and blemishes associated with acne.

SUMM . . . conjunction with concurrent or subsequent treatment by at least an additional pharmaceutical composition used to treat acne or condition the skin. In a preferred embodiment, the additional pharmaceutical composition is a topical application having at least one of: alcohol, benzoyl peroxide, erythromycin, clindamycin, tretinoin, vitamin E, and vitamin A or its derivatives; or an oral application having at least one of: erythromycin, tetracycline, isotretinoin, vitamin C, vitamin D, chaparral, dandelion root, licorice root, echinacea, kelp, cayenne, sassafras, elder flowers, pantothenic acid, para-aminobenzoic acid, biotin, choline, inositol, folic acid, calcium, magnesium, potassium and Vitamin A derivatives.

SUMM A pharmaceutical composition for treating acne and conditioning the skin cells has now been discovered. The pharmaceutical composition includes an acne reducing component in an amount sufficient to reduce the redness and blemishes associated with acne. Additionally, the present invention preferably includes a skin cell conditioning component in an amount sufficient to properly regulate the keratin and sebum production of the skin cells, thereby inhibiting or preventing the appearance of acne. The present pharmaceutical composition advantageously treats acne and conditions skin cells with reduced adverse side effects compared to conventional acne compositions and treatment methods. Also, the present invention relates to. . .

SUMM . . . present invention reduces acne in a patient by providing an acne reduction component that includes at least one of a **vitamin**A source, a carotenoid component, a vitamin B.sub.6 source, and a zinc component, in an amount sufficient to reduce the redness. .

SUMM . . . associated with acne. Furthermore, the ability of zinc to aid in wound healing, immune response, tissue regeneration, and utilization of vitamin A make it an effective component in the composition and for the treatment of acne according to the invention. The zinc. . .

Vitamin A is necessary for healthy skin
cell growth and tissue formation. Its function is to inhibit the
production of excess skin cells that eventually flake off and
tend to clog pores. The vitamin A source preferably
is vitamin A complexed to an acetate or palmitate,
and more preferably is vitamin A palmitate. The
vitamin A source is present in about 0.005 to 5 weight
percent, preferably in about 0.07 to 3 weight percent, more preferably
in about 0.1 to 2 weight percent of the composition. A unit dose of the
vitamin A source is typically about 0.1 to 5 mg,
preferably about 0.5 to 4 mg, and more preferably is about 1 to 3 mg.
Vitamin A is toxic at high levels, such that if
vitamin A is taken in doses of more than 50,000 IU per
day over a period of several months it can produce. . .

SUMM . . . such as beta-carotene, canthaxanthin, zeaxanthin, lycopen, lutein, crocetin, and capsanthin. Beta-carotene is a carotenoid that is predominantly found in the skin. Beta-carotene protects the integrity of the skin cells' structure, fights various skin conditions, and enhances the immune system. Carotenoids, preferably beta-carotene, are present in the pharmaceutical composition at about 0.1 to 10. . .

SUMM The present invention, in addition to the acne reducing component, preferably contains a skin cell conditioning component in an amount sufficient to properly regulate the sebum in the sebaceous glands

The present invention, in addition to the acne reducing component, preferably contains a **skin** cell conditioning component in an amount sufficient to properly regulate the sebum in the sebaceous glands and keratin production of the **skin** cells. This preferred embodiment of the pharmaceutical composition may be administered by any means, although oral administration is preferred.

The skin cell conditioning component activates enzymes that are involved in fat and glucose metabolism, which assists the skin cells in regulating the production of keratin and sebum. These enzymes increase the glucose intake of cells, thereby increasing the. . . Thus, the present invention attempts to prevent further acne breakouts by encouraging optimal performance of the sebaceous glands. Preferably, the skin cell conditioning component is a transition metal complex with an organic compound. Any transition metal can be used but those. . .

SUMM The **skin** cell conditioning component is present in about 0.001 to 5 weight percent, preferably about 0.002 to 3 weight percent, and more preferably about 0.005 to 1 weight percent of the pharmaceutical composition. A unit dose of the **skin** cell conditioning, such as a chromium component, is about 0.01 mg to 24 mg, preferably about 0.03 mg to 18.

SUMM The present invention more preferably contains at least one of the following: a vitamin C source, burdock root, yellow dock root, horsetail extract, a catechin-based component, a vitamin B.sub.3 source, a vitamin B.sub.2 source, and a vitamin E source to aid in the maintenance of the skin cells.

The pharmaceutical composition includes a vitamin C source that includes an ascorbic acid, or pharmaceutically acceptable salt or ester thereof, and preferably includes ascorbyl palmitate, dipalmitate L-ascorbate, . . . is calcium ascorbate. When oral formulations of the pharmaceutical composition are used, it is preferred that a non-acidic form of vitamin C be used to reduce the stomach irritation that may occur when using an acidic form. The vitamin C source is present in the pharmaceutical composition in about 1 to 30 weight percent, preferably about 5 to 25 weight percent, and more preferably about 10 to 20 weight percent. A unit dose of this vitamin C source is typically about 50 mg to 800 mg, preferably about 60 mg to 600 mg, and more preferably about. . .

SUMM Yellow Dock, whose scientific name is Rumex crispus, is often used to treat **skin** disease, especially those involving some form of inflammation. The active constituents of yellow dock are rumicin and chrysarobin. Yellow Dock. . .

SUMM . . . that contains silica, starch, volatile oils, resin, and equisetic acid as active components. This herbal extract aids in detoxifying the **skin**, and also possesses antibiotic properties. Horsetail extract is present in about 1 to 20 weight percent, preferably about 2 to. . .

SUMM . . . within the pharmaceutical composition provides powerful antioxidants to scavenge free radicals. These antioxidants are approximately 20 times more effective than vitamin C and approximately 50 times more effective than vitamin E in scavenging free radicals to prevent the skin from being damaged. The catechin-based preparation is preferably a

proanthanol or a proanthocyanidin, more preferably a proanthanol, and most preferably. . .

SUMM

carbohydrate metabolism, as well as the growth and maintenance of healthy skin. Both vitamin B.sub.2 and B.sub.3 are involved in tissue repair. Vitamin B.sub.2, also commonly known as riboflavin, is involved in both the protein and the liquid metabolism necessary to rebuild damaged skin tissues. Moreover, Vitamin

B.sub.3 acts as a vasodilator, increasing the blood flow to the skin and other tissues. Vitamin

B.sub.3 includes several vitamin B complexes, such as niacin, nicotinic acid, niacinamide, and nicotinamide. Preferably, niacinamide is used in the present.

several metabolic functions. All of the above vitamin B complexes also enhance the effectiveness of vitamin B.sub.6 in treating the skin. Preferably, the B.sub.5 source is pantothenic acid. Each of these vitamin B complexes may be found in the present pharmaceutical.

Also, a vitamin E source, which maintains the strength and proper functioning of cells and skin tissue membranes, may be included in the present invention. The vitamin E source is preferably a sulfate or succinate vitamin E complex, more preferably a D-alpha tocopherol acid succinate. The vitamin E source is present in about 1 to 30 weight percent, preferably about 6 to 25 weight percent, and more preferably about 7 to 20 weight percent of the pharmaceutical composition. The unit dose of the vitamin E source is typically about 40 mg to 650 mg, preferably about 60 mg to 500 mg, and more preferably about.

SUMM These ingredients preferably include at least one amino acid to assist in repairing acne damage to the **skin**. Preferably, two or more amino acids are used. Lysine and proline are the most preferred amino acids and are advantageously. . .

The magnitude of a prophylactic or therapeutic dose of the composition in the treatment of acne damage to **skin** will vary with the sensitivity of the patient's **skin** and the route of administration. The dose, and perhaps the dose frequency, will also vary according to the age, body. . . mg to 1,600 mg per day. In a preferred form, the invention is used to treat acne and condition the **skin** cells. The oral formulation of the present invention may be used alone or in conjunction with other acne treatments.

DETD

MG PER

PERCENT

INGREDIENTS

BY WEIGHT

CHEMICAL OR SCIENTIFIC NAME

Vitamin E Succinate (63.1%)

158.5

13.4% D-alpha tocopheryl acid succinate

L-Lysine Hcl (80.0%)

13.2%

L-Lysine hydrochloride

Calcium Ascorbate (81.0%)

154.3

13.0%

Calcium ascorbate

Burdock Root. . . Oxide (60.0%)

7.0%

Magnesium oxide

```
Zinc Ascorbate (15.0%)
                               2.1%
                                  Zinc ascorbate
Vitamin B.sub.6 (Pyridoxine HCL)
                  15.1
                            1.3%
                                  Pyridoxine hydrochloride
(82.7%)
Grape Seed Extract
                               1.1%5
                                  Proanthocyanidins
 Vitamin B. sub. 3 (Niacin)
                        12.5
                               1.1%
                                  Niacinamide
Beta Carotene (yields 1,250
                       10.0
                               0.9%

    Beta carotene

IU per tablet)
Selenomethionine (0.5%)
                                  L-selenomethionine
Biotin (1.0%)
                               0.6%
                                     7.5
                                  Biotin
Vitamin. . . Riboflavin
Vitamin B.sub.1 (Thiamine)
                       6.3
                               0.5%
                                  Thiamine
CHROMEMATE CHROMIUM GTF .TM.
                   6.3
                               0.5%
                                  Chromium polynicotinate
(0.28)
                                  Chromium organically bound
                                  to nicotinic acid (niacin,
                                    vitamin B.sub.
 Vitamin A Palmitate (yields
                               0.2%
                                    Vitamin A palmitate
1,250 IU per tablet)
Chromium Picolinate (12.0%)
                        0.1
                              0.01%
                                  Chromium picolinate
```

DETD . . . All of the panelists exhibited grade two comedonal/inflammatory acne according to the Acne Grading Scale and were free from any skin disorders other than moderate acne. The panelists were instructed to take two tablets in the morning and two in the. . .

CLM What is claimed is:
. . at least one of a zinc compound in an amount greater than 15 mg to about 96 mg or a Vitamin A source in an amount sufficient to reduce the redness and blemishes associated with acne; at least one of burdock root yellow dock root, or a catechin-based composition in an amount sufficient to facilitate maintenance of skin cells; and a skin cell conditioning component comprising a transition metal other than zinc in an amount sufficient to properly regulate the keratin and sebum production of the skin cells to inhibit the appearance of acne.

<sup>6.</sup> The pharmaceutical composition of claim 5, wherein the

vitamin A source comprises vitamin A
complexed with an acetate or palmitate, the carotenoid component
comprises beta-carotene, the vitamin B.sub.6 source comprises a
pyridoxine, and the. . .
7. The pharmaceutical composition of claim 6, wherein the
vitamin A source is vitamin A

palmitate present in about 0.005 to 5 weight percent, beta-carotene is present in about 0.1 to 10 weight percent, the. . . 9. The pharmaceutical composition of claim 1, further comprising at least one of a vitamin C source, horsetail extract, a vitamin B.sub.1 source, a vitamin B.sub.2 source, a vitamin B.sub.3 source, a vitamin B.sub.5 source, and a vitamin E source, all in an amount sufficient to facilitate maintenance of skin cells.

- 10. The pharmaceutical composition of claim 9, wherein the vitamin C source comprises ascorbic acid or ascorbate, the catechin-based composition comprises a proanthanol or proanthocyanidin, the vitamin B.sub.l source comprises thiamin, the vitamin B.sub.2 source comprises riboflavin, the vitamin B.sub.3 source comprises niacinamide, the vitamin B.sub.5 source comprises pantothenic acid, and the vitamin E source comprises a sulfate or succinate vitamin E complex.
- 11. The pharmaceutical composition of claim 10, wherein the vitamin C source is calcium ascorbate present in about 1 to 30 weight percent, the burdock root is present in about 1. . . in about 0.05 to 5 weight percent, the thiamin is present in about 0.05 to 5 weight percent and the vitamin E source is vitamin E succinate present in about 1 to 30 weight percent.
- . one amino acid component, a magnesium component, a selenium component, and biotin in an amount sufficient to facilitate repair of skin damaged by acne.
- 15. A method for conditioning skin cells in a patient which comprises administering: an acne reduction component comprising at least one of a zinc compound or a Vitamin A compound; at least one of burdock root, yellow dock root, or a catechin-based composition in an amount sufficient to facilitate maintenance of skin cells; and a skin cell conditioning component comprising a transition metal other than zinc, said components administered in an amount therapeutically effective to regulate the keratin and sebum production of the skin cells and to reduce the redness and blemishes associated with acne.
- . conjunction with concurrent or subsequent treatment by at least an additional pharmaceutical composition used to treat acne or condition the  ${\bf skin}$ .
- . wherein the additional pharmaceutical composition is: a topical application comprising at least one of: alcohol, benzoyl peroxide, erythromycin, clindamycin, tretinoin, vitamin E, and vitamin A or its derivatives; or an oral application comprising at least one of: erythromycin, tetracycline, isotretinoin, vitamin C, vitamin D, chaparral, dandelion root, licorice root, echinacea, kelp, cayenne, sassafras, elder flowers, pantothenic acid, para-aminobenzoic acid, biotin, choline, inositol, folic acid, calcium, magnesium, potassium and Vitamin A derivatives.

L3 ANSWER 9 OF 17 USPATFULL

TI Pharmaceutical compositions and methods for improving wrinkles and other skin conditions

PI US 5804594

AΒ

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This application relates to a pharmaceutical composition for the prevention and treatment of skin conditions in a patient having a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the skin, a primary antioxidant component in an amount sufficient to substantially inhibit the formation of collagenase and elastase, at least one amino acid component in an amount sufficient to assist in the thickening of the skin, and at least one transition metal component in an amount effective to bind collagen and elastic fibers and rebuild skin . In one preferred form, the composition further includes a catechin-based preparation, a glucosamine or a pharmaceutically acceptable salt or ester. . . a chondroitin or a pharmaceutically acceptable salt or ester thereof. In a more preferred form, the invention further includes a vitamin E source, a cysteine source, a vitamin B.sub.3 source, quercetin dihydrate, pyridoxal 5 phosphate-Co B.sub.6, a methionine source, and a vitamin A source. The invention further relates to a method for the prevention or treatment of skin conditions by administering the pharmaceutical composition in an amount therapeutically effective to modify the thickness of the skin to prevent or treat at least one skin condition.

SUMM . . . well as methods, to supplement collagen and elastic tissues and thicken the dermis for the treatment of wrinkles and other **skin** conditions.

SUMM Human skin is a composite material of the epidermis and the dermis. The topmost part of the epidermis is the stratum corneum. This layer is the stiffest layer of the skin, as well as the one most affected by the surrounding environment. Below the stratum corneum is the internal portion of. . . the dermis is the papillary dermis, which is made of relatively loose connective tissues that define the micro-relief of the skin. The reticular dermis, disposed beneath the papillary dermis, is tight, connective tissue that is spatially organized. The reticular dermis is . .

The principal functions of the **skin** include protection, excretion, secretion, absorption, thermoregulation, pigmentogenesis, accumulation, sensory perception, and regulation of immunological processes. These functions are detrimentally affected by the structural changes in the **skin** due to aging and excessive sun exposure. The physiological changes associated with **skin** aging include impairment of the barrier function and decreased turnover of epidermal cells, for example. [Cerimele, D., et al., Br.. . .

The mechanical properties of the skin, such as elasticity, are controlled by the density and geometry of the network of collagen and elastic fiber tissue therein. Damaged collagen and elastin lose their contractile properties, resulting in skin wrinkling and skin surface roughness. As the skin ages or becomes unhealthy, it acquires sags, stretch marks, bumps, bruises or wrinkles, it roughens, and it has reduced ability to synthesize Vitamin

D. Aged skin also becomes thinner and has a flattened dermoepidermal interface because of the alterations in collagen, elastin, and glycosaminoglycans. [Fenske, N. . . .

SUMM A variety of vitamins and minerals have in individually been administered to treat certain **skin** and other problems that occur when the patient has a deficiency of that vitamin or mineral.

Vitamin A, for example, assists in the treatment of acne and to facilitate wound healing; vitamin C

(ascorbic acid) assists in the prevention of skin bruising and wound healing; vitamin E is an antioxidant; and copper assists in the treatment of elastic tissue defects. [Neldner, K. H., Amer. Acad. Derm. Annl. Mtg., Wash D.C., Dec. 6, 1993]. Topical use of vitamin C is also believed to ward off sun damage, reduce breakdown of connective tissues, and possibly promote collagen synthesis. [Dial, W., Medical World News, p. 12, March 1991]. Vitamin E is used topically as an anti-inflammatory agent, for enhancement of skin moisturization, for UV-ray protection of cells, and for retardation of premature skin aging.

- SUMM . . . metabolism of glycosaminoglycans under the influence of herbal and other anti-inflammatory agents has been examined by measuring glycosaminoglycans in the skin, liver, kidney, and spleen after administration of several compounds. [Reddy, G. K., et al., Biochem. Pharmacology, 38(20):3527-3534 (1989)].
- SUMM . . . a patient, various of the above ingredients have been combined to form pharmaceuticals designed to prevent and treat certain cellular, skin, and other conditions. For example, U.S. Pat. No. 3,773,930 discloses a low residue, dietary composition having at least one amino.
- SUMM U.S. Pat. No. 4,414,202 discloses a composition for the treatment of **skin** wounds with a buffered salt solution having a pH between 6 to 7.8 and administering a starch hydrolysate compound, and. . .
- SUMM U.S. Pat. No. 4,424,232 discloses a topical composition for the treatment of herpes simplex, cold sores, lesions, and other painful skin conditions including L-lysine, gibberellic acid, and urea in an inert carrier having water. The composition may also include L-ascorbic acid, . . .
- SUMM U.S. Pat. No. 5,198,465 discloses a composition for treating precursor deficiencies in the synthesis of collagen with proline, glycine, lysine, vitamin C, and one or more compounds selected from a-ketoglutaric acid, methionine, cysteine, cystine, valine, and pharmaceutically acceptable diluents and excipients.
- SUMM . . . complexes; an enzyme producer such as an amino acid like glutamic acid; an herbal antispasmodic substance like Valerian root; and vitamin C.
- SUMM U.S. Pat. No. 5,415,875 discloses a method of suppressing formation of lipid peroxide and removing peroxide by applying to the **skin** a decomposed product of shell membrane and tocopherol and derivatives. Lysine, proline, **Vitamin C**, for examples, are listed among a vast genus of optional additives.
- SUMM The above references, however, do not teach pharmaceutical compositions or methods for improving skin wrinkles along with other conditions, such as skin elasticity and softness. Thus, it is desired to find a pharmaceutical composition and a method for the prevention and treatment of wrinkles and other skin conditions. The present invention advantageously provides pharmaceutical compositions, as well as methods of treatment comprising the administration of such compositions, to repair skin for the prevention and treatment of wrinkles and other skin disorders.
- The present invention relates to a pharmaceutical composition for the prevention and treatment of **skin** conditions in a patient having a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the **skin**, a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase, at least one amino acid component in an amount sufficient to assist in the thickening of the **skin**, and at least one transition metal component in an amount effective to bind collagen and elastic fibers and rebuild **skin**
- SUMM In another preferred embodiment, the composition further includes a

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vitamin E source, a cysteine source, a vitamin
      B.sub.3 source, quercetin dihydrate,
      pyridoxal 5 phosphate-Co B.sub.6, a methionine source, and a
      vitamin A source. In a more preferred embodiment, the
      vitamin E is D-alpha tocopheryl acid succinate present
       in about 1 to 15 weight percent, the vitamin B.
       sub.3 is niacinamide present in about 0.5 to 15 weight
      percent, the vitamin A is vitamin
      A palmitate present in about 0.1 to 5 weight percent, the
       cysteine is N-acetyl cysteine present in about 1 to 10.
SUMM
      The invention further relates to a method for the prevention or
      treatment of skin conditions, wherein the skin has a
       thickness of dermis and collagen, which includes administering the
      pharmaceutical composition above in an amount therapeutically effective
      to modify the thickness of the skin to prevent or treat at
      least one skin condition.
SUMM
      In one embodiment according to the invention, the skin
       condition treated is at least one of wrinkles, fine lines, thinning,
       reduced skin elasticity, reduced skin moisture,
       spider veins, senile purpura, sun damaged skin, aging
      skin, or rough skin. In another embodiment, the
      composition is administered orally. In a preferred embodiment, the
      composition is administered as a tablet or.
                                                   . .
       . . . conjunction with concurrent or subsequent treatment by at least
SUMM
      one additional pharmaceutical composition for the prevention or
       treatment of a skin condition.
      A formulation for the reduction of wrinkles and the improvement of other
SUMM
       skin conditions, such as increased skin elasticity and
       skin softness, has now been discovered. Moreover, the prevention
      or treatment of unhealthy skin, such as aged skin or
       skin overexposed to sunlight, may advantageously be accomplished
      by the administration of the pharmaceutical composition of the present
      invention to a. . . pharmaceutical composition includes the
       combination of a number of different components which interact to
      provide the desired improvements to the skin.
SUMM
      The advantageous pharmaceutical composition of the present invention
      prevents and improves skin conditions by using a sufficient
      amount of at least one sugar compound which is converted into
      glycosaminoglycans in the bloodstream,. . . supplementing collagen
      and elastic tissues. A thicker dermis desirably reduces the wrinkling
      and lines that occur when areas of the skin become thin.
      Various amino acids such as lysine, proline and cysteine assist in the
       thickening of the dermis, supplementing of collagen and elastic tissues
      and, consequently, reduction of wrinkles and other skin
       conditions. Additionally, antioxidants, such as vitamin
      c, inhibit collagenase and elastase, enzymes that break down
       collagen and elastic tissues. These antioxidants assist in the
      prevention of additional wrinkles and facilitate the healing of
       skin tissues. Finally, transition metal components are included
      to bind collagen fibers and inhibit elastase, an enzyme that also breaks
SUMM
      The pharmaceutical composition includes a primary antioxidant, which
      typically is a {\bf vitamin}\ {\bf C} source and preferably is
      ascorbic acid, or a pharmaceutically acceptable salt or ester thereof,
       and more preferably is ascorbyl palmitate,. . . or mixtures thereof.
      When oral formulations of the pharmaceutical composition are used, it is
      preferred that a non-acidic form of vitamin C be
      used to reduce the stomach irritation that may occur when using an
      acidic form. The vitamin C source is present in the
      pharmaceutical composition in about 5 to 50 weight percent, preferably
      about 7 to 40 weight percent, and more preferably about 10 to 25 weight
      percent. A unit dose of this primary vitamin C
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source is typically about 40 mg to 400 mg, preferably about 60 mg to 300
       mg, and more preferably about 80 to 150 mg. Vitamin C
       is also approved by the FDA and has wide consumer acceptance, so that it
       can be used in amounts as.
       The pharmaceutical composition also includes at least one amino acid to
SUMM
       assist in thickening the skin. Preferably two or more amino
       acids are used in combination. Either the L- or D- forms of amino acids
             . or more transition metal compounds are included in an amount
SUMM
       effective to bind collagen and elastic tissue to rebuild the
       skin. Certain transition metal compounds inhibit the elastase
       enzyme to inhibit collagen and elastic tissue breakdown. Preferred
       transition metals include zinc,.
       . . assist in binding collagen and elastic fibers, which both
SUMM
       assists in the prevention of wrinkles and the rebuilding of wrinkled
       skin. The zinc component may be any zinc compound or
       pharmaceutically acceptable salt thereof, but more preferably is a zinc
       complexed.
SUMM
            . or pharmaceutically acceptable salt thereof, but more
       preferably is a manganese component which is at least partially
       complexed with a vitamin C source, and most
       preferably is manganese ascorbate or manganese ascorbic acid, wherein
       the manganese is typically present in about 5 to 20 weight percent of
       the complex. When complexed with vitamin C, this
       vitamin C source may be included in the overall
       percentage of vitamin C in the pharmaceutical
       composition. The manganese component is present in about 1 to 10 weight
       percent, more preferably about 2. .
       The catechin-based preparation, similar to vitamin C
SUMM
       , inhibits elastase and collagenase, which is another enzyme that attacks elastic tissue and collagen. The catechin-based preparation is
       preferably a.
             . 90 weight percent of the salt. The glucosamine content of this
SUMM
       component contributes to the formation of glycosoaminoglycans in the
       skin. The chondroitin component preferably is present as a
       sulfate or succinate, and more preferably is chondroitin sulfate,
       wherein the chondroitin.
       In a more preferred form, several optional additives are included in the
SUMM
       pharmaceutical composition, such as a vitamin E
       source, a vitamin B.sub.3
       source, quercetin powder, pyridoxal 5 phosphate-Co B.sub.6, and a
       vitamin A source. The vitamin E
       preferably is a sulfate or succinate vitamin E
       complex, and more preferably is D-alpha tocopheryl acid succinate. The
       vitamin E source is present in about 1 to 15 weight
       percent, preferably about 2 to 12 weight percent, and more preferably.
             10 weight percent of the composition. In any event, no more than
       1,500 IU should be ingested per day, as Vitamin E
       becomes toxic at higher doses. The vitamin B.
       sub.3 source preferably is niacinamide, and the source
is present in about 0.5 to 15 weight percent, preferably about 1 to 12
       weight percent, and more preferably about 1.5 to 10 weight percent of
       the composition. The vitamin A source preferably is
       vitamin A palmitate, and the source is present in
       about 0.1 to 5 weight percent, preferably 0.2 to 3 weight percent, and
       more preferably 0.3 to 1 weight percent of the composition. In the more
       preferred form, the amount of vitamin A dosage is
       about 500,000 IU / gram per unit dose. Vitamin A is
       toxic at high levels, such that no more than 400,000 IU should be
       cumulatively ingested per day for greater.
SUMM
        . . amount" means that amount of the pharmaceutical composition
       that provides a therapeutic benefit in the treatment, prevention, or
```

management of **skin** wrinkles and other **skin** conditions.

condit DETD	ions.		
Ingredient	Weight Percent (% w/w)	Amount (mg)	Chemical or Scientific Name (if different)
		····· · · · · · · · · · · · · · · · ·	
N-Acetylgluco	samine 17.1	140	N-Acetyl D- Glucosamine
Vitamin C (	81.2% 15	123.2	
Ascorbic Acid L-Lysine (80%	•		•
L-Dysine (00°	12.2	100	L-Lysine hydrochloride
L-Proline D-Glucosamine	11 Sulfate	90	
/750\	6.5	53.3	
(75%) Chondroitin S	ulfate 6.1	50	
(80%)			
<b>Vitamin E</b> S	uccinate 4.3	39.7	Dalpha. tocopheryl acid succinate
Zinc monometh	ionine 3.7	30	Zinc DL-
(20%) N-Acetyl Cyst		20	methionine
Manganese Asc	3.7 orbate	30	
(13% Mn)	2.8	23.1	
Vitamin B.s			
Niacinamide	2.4	20	Niacinamide
Quercetin Pow	der		
	2.4	20	Quercetin dihydrate
Grape Seed Ex	tract 0.9	7.5	Proanthocyanidin
Pyridoxal 5 Phosphate-Co	0.6	5	P-5-P monohydrate
Selenoinethio		4	L-
(0.5%) Vitamin A P	0.5	4	selenomethionine
Vitamin A P	0.5	4	
(500,000 IU/G			
Copper Sebaca	0.4	2.9	
Red beet root	powder 6.1	50	Beta vulgaris
Stearic acid Sorbitol	1.5 1.3	12	rubra
DETD firmne A seve study,	. 73 femss, and pn day con where su	resence o ditioning bjects we	cts to determine the effects on the elasticity, f fine lines and wrinkles of the <b>skin</b> .  period was used prior to initiation of the re instructed to discontinue use fine lines, and wrinkles were

assessed by taking Silflo replicas of the periorbital area (crow's feet) at each of the. . . replicas, were illuminated at a precisely defined angle of 350 to create shadows for analysis by shades of gray. The skin topography is defined by the: (a) number of wrinkles; (b) total area of wrinkles; (c) total length of wrinkles; (d). . .

- DETD . . . is a function of the length of treatment as indicated above. This strongly suggests the treatment has imparted an improved skin infrastructure by beneficially affecting the dermis of the skin.
- DETD The Ballistometer is an instrument designed to evaluate in vivo, in a non-invasive manner, the viscoelastic properties of the skin.

  It analyzes the bounce pattern displayed by a probe that is allowed to impact on the skin. The kinetic energy of the probe striking the skin is stored by the elastic components of the skin and released back to make the probe rebound to a lower height. The height to which the probe will rebound depends upon the amount of stored energy lost in shear viscosity within the skin
- DETD The capacity of the **skin** to absorb mechanical energy may thus be measured. Although it is unclear exactly which layer, or layers, of the **skin** are responsible, the mechanical properties of the dermis/epidermis layers are controlled by the density and geometry of the network of. . .
- DETD . . . less of the energy of the striking probe was restored, thus, a greater amount of energy was dissipated in the **skin**. This suggests the **skin** became softer and more yielding during the test period.
- The Cutometer is a commercially available instrument (Courage & Khazaka, Germany) designed to measure the mechanical properties of the skin in a non-invasive manner. It measures the vertical deformation of the skin's surface when pulled by vacuum suction (500 mm Hg) through the small aperture (2 mm) of a probe and the depth of penetration of the skin into the probe optically with an accuracy of 0.01 mm. The probe is attached to a computer, which completely controls probe operation and plots skin deformation as a function of time. From this curve, a number of variables can be extrapolated to estimate the elastic, viscoelastic, and purely viscous behavior of the skin.
- DETD . . . final distension (U.sub.f), measured at 10 seconds; and (d) immediate retraction (U.sub.r). The deformation parameters are extrinsic parameters dependent on **skin** thickness, and a variety of biologically important ratios were calculated: (a) U.sub.r /U.sub.f, a measure of net elasticity of the **skin**; (b) U.sub.r /U.sub.c, the biological elasticity, or measurement of the ability of the **skin** to regain its initial configuration after deformation; and (c) U.sub.v /U.sub.c, the viscoelastic to elastic ratio, where an increase in. . .
- DETD . . . distension (U.sub.v) decreased a significant 16 percent (p<0.04) after 5 weeks of treatment. This parameter reflects viscoelastic properties of the  ${\bf skin}$  and, thus, the behavior of the dermis. After 5 weeks, there were no statistically significant changes in U.sub.c, the immediate. . .
- The general appearance of soft, smooth skin depends largely on the presence of an adequate amount of water in the stratum corneum. The Corneometer is a commercially available instrument (Courage & Khazaka, Germany) to measure the changes in capacitance of the skin resulting from changes in the degree of hydration. It is particularly sensitive to low levels of hydration, and uses measurements of arbitrary units of skin hydration (H) to express capacitance.
- DETD . . . moisturizing agents and humectants. Thus, the measurements with the Ballistometer and Cutometer indicate changes occurred in deeper layers of the **skin**, rather than the superficial stratum

corneum. Table IV shows no significant changes in the hydration of the stratum corneum following. . .

DETD

TABLE IV

Corneometer Readings

Skin Hydration (H) Mid-Baseline

Final-Baseline

Control

Treated Control Treated

Average -5 -7 -8 -4 Standard Deviation 6 7 5 7 p value p < . . .

CLM What is claimed is:

- 1. An orally administered pharmaceutical composition for the prevention and treatment of **skin** conditions in a patient comprising the following components: a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the **skin**; a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase; at least one amino acid component in an amount sufficient to assist in the thickening of the **skin**; at least one transition metal component in an amount effective to bind collagen and elastic fibers and thicken **skin**; and a catechin-based component present in an amount sufficient to inhibit the presence of anti-collagen enzyme in the **skin**.
- 10. The pharmaceutical composition of claim 7, further comprising a vitamin E source, a cysteine source, a vitamin B.sub.3 source, quercetin dihydrate, pyridoxal 5 phosphate-Co B.sub.6, a methionine source, and a vitamin A source.
- 11. The pharmaceutical composition of claim 10, wherein the vitamin E is D-alpha tocopheryl acid succinate present in about 1 to 15 weight percent, the vitamin B. sub.3 is niacinamide present in about 0.5 to 15 weight percent, the vitamin A is vitamin A palmitate present in about 0.1 to 5 weight percent, the cysteine is N-acetyl cysteine present in about 1 to 10. . . . 12. An orally administered pharmaceutical composition for the prevention and treatment of skin conditions in a patient comprising: an N-acetylglucosamine compound, or a pharmaceutically acceptable salt or ester thereof, present in about 5. . . metal compound is zinc, manganese, or copper, or mixtures thereof, present in about 0.5 to 15 weight percent to thicken skin.
- 13. A method for the prevention or treatment of **skin** conditions, wherein the **skin** has a thickness of dermis and collagen, which comprises orally administering to a patient a pharmaceutical composition comprising: a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the **skin**; a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase; at least one amino acid component in an amount sufficient to assist in the thickening of the **skin**; and at least one transition metal component in an amount effective to bind collagen and elastic fibers and thicken **skin**, said composition administered in an amount therapeutically effective to modify the thickness of the **skin** to prevent or treat at least one **skin** condition.

- 14. The method of claim 13, wherein the **skin** condition prevented or treated is at least one of wrinkles or the appearance thereof, fine lines or the appearance thereof, thinning, reduced **skin** elasticity, reduced **skin** moisture, spider veins, senile purpura, sun damaged **skin**, aging **skin** or rough **skin**.
- . conjunction with concurrent or subsequent treatment by at least one additional pharmaceutical composition for the prevention or treatment of a skin condition.
- . comprising providing a catechin-based component present in an amount sufficient to inhibit the presence of an anti-collagen enzyme in the skin.
- L3 ANSWER 10 OF 17 USPATFULL
- TI **Skin** protection, fragrance enhancing and vitamin delivery composition
- PI US 5728372 19980317 <--
- The present invention provides a composition having enhanced skin protection against ultraviolet rays comprising at least one sunscreen composition and at least one polysaccharide alkylether which includes at least. . . hydroxyl group substituted with a saturated C.sub.1 -C.sub.24 alkyl chain. The present invention also provides a method for enhancing the skin protection properties of sunscreen compositions. The present invention further provides an anhydrous composition for delivering one or more vitamins to the skin including at least one vitamin composition and at least one polysaccharide alkylether having at least two different moieties and at. . . saturated C.sub.1 -C.sub.24 alkyl chain. The present invention also provides a method for delivering one or more vitamins to the skin.
- SUMM This invention is directed to a composition having enhanced skin protection properties against ultraviolet rays, and a method of enhancing the skin protection properties of sunscreen compositions. This invention is also directed to a composition for extending the longevity of fragrance on the skin, and a method for extending the longevity of fragrance on the skin. This invention is also directed to an anhydrous composition for delivering one or more vitamins to the skin, and a method for delivering one or more vitamins to the skin.
- SUMM The damaging effect of the sun's ultraviolet radiation on the skin is well known. Accordingly, many skin protection products have been developed which contain various materials intended to block or absorb ultraviolet rays, thereby preventing or lessening damage to the skin. Typically, such products are oil-in-water or water-in-oil emulsions and anhydrous systems containing sunscreens or ultraviolet radiation filters, and the compositions are topically applied to the skin. The relative skin protection afforded by such compositions is typically measured by means of determining a "sun protection factor" or SPF for the. . .
- SUMM . . . that there is a relationship between the rheological properties of such emulsions and the SPF of the composition. Since the **skin** is not a flat surface, but rather has a topography made up of irregular peaks and valleys, it is believed. . . emulsion are relatively minimal. Oils typically exhibit Newtonian viscosity (i.e., non-shear sensitive), which is not very effective in covering the **skin**. Accordingly, the rheological properties of traditional **skin** protection emulsions based upon water-soluble rheological additives are greatly reduced as water evaporation from the **skin** takes

place. The remaining oil phase provides a less effective covering of the **skin**, with concurrent reduction in protection from ultraviolet rays. Thus, it would be advantageous to prepare a **skin** protection composition which is an emulsion having enhanced SPF and which avoids the above-described problems.

SUMM

- . . . alkyl chain have enhanced SPF properties. Accordingly, it is one object of this invention to provide a composition having enhanced skin protection properties from ultraviolet radiation. It is another object of this invention to provide a method of enhancing the skin protection properties from ultraviolet radiation using such a composition. It is a feature of the composition and method of this. chain. This invention is advantageous in that the use of the oil soluble polymer enhances the SPF capability of the skin protection composition. While not wishing to be bound by any theory, it is believed that incorporation of this oil soluble polymer into the oil phase increases viscosity and provides film forming properties that enhance SPF activity on skin.
- The use of various fragrance-bearing compositions on the skin has been known for centuries. However, improving the duration of fragrances on the skin has always posed a challenge. In the past, attempts have been made to introduce various materials into fragrance compositions to. . . compositions, and changes in the character of the fragrance have all impaired improvement of the longevity of fragrance on the skin. Accordingly, it would be advantageous to prepare a composition capable of imparting fragrance to the skin and capable of extending the longevity of the fragrance on the skin.
- SUMM . . . group substituted with a saturated C.sub.1 -C.sub.24 alkyl chain are capable of extending the longevity of the fragrance to the skin. Accordingly, it is another object of this invention to provide a composition for extending the longevity of fragrance on the skin. It is another object of this invention to provide a method of extending the longevity of fragrance on the skin using such a composition. It is a feature of the composition and method of this invention that the composition contains. . . advantageous in that the use of the polysaccharide alkylether oil soluble polymer extends the longevity of fragrance imparted to the skin by the fragrance composition.
- The delivery of various vitamins to the skin is known to be SUMM beneficial. For example, vitamin C (i.e., ascorbic acid) and vitamin E (i.e., tocopherol) are well known skin care ingredients with proven beneficial free radical scavenger and antioxidant properties. However, to be effective these and other vitamins must be delivered to the skin in the active form. For example, vitamin E is oil soluble, but vitamin C is water soluble and is very unstable in water, degrading very rapidly. Thus, effective delivery of vitamin C to the skin in an aqueous system is very difficult to achieve. Accordingly, the use of anhydrous or essentially anhydrous systems to deliver effective amounts of vitamin C to the skin have been attempted. Such systems have employed materials such as petrolatum, waxes, fatty alcohols, fatty acids, polyethylenes and low HLB. . . properties. Thus, it would be advantageous to prepare an anhydrous composition capable of delivering one or more vitamins to the skin which has good stability and cosmetic application properties. SUMM
  - . . . saturated C.sub.1 -C.sub.24 alkyl chain are capable of delivering the vitamin, including combinations of vitamins C and E, to the **skin**. Accordingly, it is yet another object of this invention to provide an anhydrous composition for delivering one or more vitamins to the **skin**. It is another object of this invention to provide a method for delivering one or more vitamins to the

skin using such a composition. It is a feature of the
composition and method of this invention that the composition contains.
. use of the polysaccharide alkylether oil soluble polymer provides
a stable, cosmetically acceptable vehicle for delivery of vitamins to
the skin.

SUMM A composition for having enhanced skin protection from ultraviolet rays comprises at least one sunscreen composition and at least one polysaccharide alkylether comprising at least two. . . sunscreen composition comprises one or more materials capable of filtering, blocking or absorbing ultraviolet rays. A method for enhancing the skin protection properties of sunscreen formulations against ultraviolet rays comprises applying to the skin a composition comprising at least one sunscreen composition and at least one polysaccharide alkylether comprising at least two different moieties. . .

SUMM A composition for extending the longevity of fragrance on the skin comprises at least one fragrance composition and at least one polysaccharide alkylether comprising at least two different moieties and at. . . composition comprises one or more materials having a fragrant odor. A method for extending the longevity of fragrance on the skin comprises applying to the skin a composition comprising at least one fragrance composition and at least one polysaccharide alkylether comprising at least two different moieties. .

An anhydrous composition for delivering one or more vitamins to the skin comprises at least one vitamin and at least one polysaccharide alkylether comprising at least two different moieties and at least one hydroxyl group substituted with a saturated C.sub.l -C.sub.24 alkyl chain. The composition for delivering vitamins to the skin comprises at least one vitamin. For example, the composition may comprise vitamin C, vitamin

E, or a combination thereof. A method for delivering one or more vitamins to the skin comprises applying to the skin a composition comprising at least one vitamin and at least one polysaccharide alkylether comprising at least two different moieties and. . .

SUMM All of these compositions are most preferably topically applied to the skin. The polysaccharide alkyl ether has a weight average molecular weight in the range of 1 to 1,000,000, preferably 1 to. .

SUMM The **skin**-protection enhancing composition of this invention comprises at least one sunscreen composition and at least one oil soluble polymer which is. . .

SUMM . . . MCX, manufactured by Givaudan, and UVINUL M-40, a benzophenone-3 product manufactured by BASF. The sunscreen composition is employed in the **skin**-protection enhancing composition in a concentration range approved by the United States Food and Drug Administration (FDA). A sunscreen such as. . . OMC is employed in a concentration range of 2 to 7.5 weight percent, based on the total weight of the **skin** protection formulation. Benzophenone-3 is employed in a concentration range of 2 to 6, preferably 2 to 3 weight percent, based on the total weight of the **skin** protection formulation.

SUMM . . . Inc. under the AQUALON trade name, most preferably AQUALON AQU-D-3360-L and AQU-3360-H. The polysaccharide alkylether is employed in the enhanced **skin** protection composition in a concentration range of about 0.5 to 10 weight percent, based upon the total weight of the **skin** protection formulation. The invention may be employed in an anhydrous sun protection formulation as well as in oil-in-water or water-in-oil. . .

SUMM The following examples illustrate various preferred embodiments of the enhanced **skin** protection composition of this invention. It will be understood that the following examples are illustrative and are

not meant to.

. . . being bound by any one theory, it is expected that use of the DETD polysaccharide alkylether oil soluble polymer in the skin protection composition of this invention enables the oil-soluble ultraviolet filter or sunscreen material contained in the composition to be distributed more uniformly on the skin topography. It is also expected that the rheological properties are improved and made more flexible with respect to oil phases. . . composition. It is also expected that use of the polysaccharide alkylether prolongs the activity of the sunscreen composition on the skin, and reduces the penetration of oil-soluble sunscreen composition into the skin , thereby lowering the potential of skin irritation due to such penetration. It is also expected that use of the polysaccharide alkylether will enable the level or concentration of the sunscreen or ultraviolet radiation filter material to be reduced in the skin

protection composition, thereby reducing the cost and possible harmful side effects of such materials. It is also expected that use of the polysaccharide alkylether will impart improved water-resistant properties to the skin-protection composition, thereby enhancing its use at the beach, pools, while swimming and the like.

. . . polysaccharide alkylether employed in the fragrance extending DETD composition of this invention is as described above with respect to the enhanced skin protection composition embodiment of this invention. The absence of any chemical odor in the oil soluble and lipophilic polymer makes.

. . . fragrance duration. Formula D prepared in accordance with the DETD invention was found to exhibit significantly longer fragrance duration on the skin as compared with control formula E.

. . . Preliminary evaluation tests confirmed that formulation B DETD prepared in accordance with the invention exhibited significantly longer fragrance duration on the skin.

. . alkylether employed in the vitamin delivery composition DETD embodiment of this invention is as described above with respect to the enhanced skin protection composition and fragrance-enhancing embodiments of this invention. The oil soluble polymer may be present in the vitamin-delivery composition embodiment.

Vitamins which may be employed in this embodiment of the invention DETD include, but not limited to, vitamin A, pro vitamin A, vitamin B.sub.1, vitamin B.sub.2, vitamin B.sub.3, vitamin B.sub.4,

vitamin B.sub.5, vitamin B.sub.6, vitamin B.sub.12, vitamin

C, vitamin D, vitamin D

.sub.2, vitamin D.sub.3, vitamin E

, vitamin F, vitamin K.sub.1 and combinations and derivatives thereof. Preferred vitamins include vitamins C and E, as well as derivatives and combinations thereof. In a particularly preferred embodiment, the invention comprises both vitamin C and

vitamin E. The vitamins may be present in a concentration from about 0.5-50 percent by weight, preferably 0.5-10percent by weight, based. . .

DETD

Vitamin (Phase	Suspension Ingredients	% Wt		
A	Eutanol G	87.40		
A	AQU-D-3360-	AQU-D-3360-H		
		7.60		
В	Micronized	5.00		
	Ascorbic Acid			
	Total	100.00		
Viscosity (cps)		83,000		

DETD  Vitamin C and E Suspension						
Phase	<del>-</del>	A Wt. %	B Wt. %			
A	Finsolv TN	64.50	41.00			
A	Tocopherol	1.00	1.00			
A	Wickenol 151		10.00			
A	Cyclomethicone	21.50	35.00			
В	AQU-D-3360-H	8.00	8.00			
С	Vitamin C	5.00	5.00			
	TOTAL	100.00	100.00			
Viscosity						
-	· 	99,000	92,000			
(cps)						

DETD . . . together with a propeller mixer. AQU-D-3360-H was added to the other Phase A ingredients while stirring with a propeller mixture.

Vitamin C was added to the resulting mixture while stirring with a propeller mixer.

DETD . . . water absorption properties, the bioavailability of the vitamin or vitamins is enhanced upon application of the vitamin suspension to the **skin**.

CLM What is claimed is:

- 1. A composition having enhanced **skin** protection against ultraviolet rays comprising at least one sunscreen composition and at least one polysaccharide alkylether comprising at least two. . .
- 12. A method for enhancing the **skin** protection properties of sunscreen compositions against ultraviolet rays comprising applying to the **skin** a composition comprising at least one sunscreen composition and at least one polysaccharide alkylether comprising at least two different moieties. . .
- 23. An anhydrous composition for delivering one or more vitamins to the **skin** comprising at least one vitamin composition and at least one polysaccharide alkylether comprising at least two different moieties and at. . .
- 35. A method for delivering one or more vitamins to the **skin** comprising applying to the **skin** a composition comprising at least one vitamin composition and at least one polysaccharide alkylether comprising at least two different moieties. . .
- 47. A method according to claim 35, wherein the vitamin is  ${\bf vitamin}\ {\bf C}.$
- L3 ANSWER 11 OF 17 USPATFULL
- TI Skin protection, fragrance enhancing and vitamin delivery composition
- PI US 5728371 19980317 <--
- AB The present invention provides a composition for extending the longevity of the fragrance on the **skin** which comprises at least one fragrance composition and at least one polysaccharide alkylether which includes at least two different moieties. . . saturated C.sub.l -C.sub.24 alkyl chain. The present invention also provides a method for extending the longevity of fragrance on the **skin** which involves applying to the **skin** a composition including at least one fragrance composition and at least one polysaccharide alkylether having at least two different moieties. . .
- SUMM This invention is directed to a composition having enhanced **skin** protection properties against ultraviolet rays, and a method of enhancing the **skin** protection properties of sunscreen compositions. This invention is also directed to a composition for extending the longevity of fragrance on the **skin**, and a method

for extending the longevity of fragrance on the **skin**. This invention is also directed to an anhydrous composition for delivering one or more vitamins to the **skin**, and a method for delivering one or more vitamins to the **skin**.

SUMM

The damaging effect of the sun's ultraviolet radiation on the skin is well known. Accordingly, many skin protection products have been developed which contain various materials intended to block or absorb ultraviolet rays, thereby preventing or lessening damage to the skin. Typically, such products are oil-in-water or water-in-oil emulsions and anhydrous systems containing sunscreens or ultraviolet radiation filters, and the compositions are topically applied to the skin. The relative skin protection afforded by such compositions is typically measured by means of determining a "sun protection factor" or SPF for the. . .

SUMM

. . . that there is a relationship between the rheological properties of such emulsions and the SPF of the composition. Since the **skin** is not a flat surface, but rather has a topography made up of irregular peaks and valleys, it is believed. . . emulsion are relatively minimal. Oils typically exhibit Newtonian viscosity (i.e., non-shear sensitive), which is not very effective in covering the **skin**. Accordingly, the rheological properties of traditional **skin** protection emulsions based upon water-soluble rheological additives are greatly reduced as water evaporation from the **skin** takes place. The remaining oil phase provides a less effective covering of the **skin**, with concurrent reduction in protection from ultraviolet rays. Thus, it would be advantageous to prepare a **skin** protection composition which is an emulsion having enhanced SPF and which avoids the above-described problems.

SUMM

one object of this invention to provide a composition having enhanced skin protection properties from ultraviolet radiation. It is another object of this invention to provide a method of enhancing the skin protection properties from ultraviolet radiation using such a composition. It is a feature of the composition and method of this. chain. This invention is advantageous in that the use of the oil soluble polymer enhances the SPF capability of the skin protection composition. While not wishing to be bound by any theory, it is believed that incorporation of this oil soluble polymer into the oil phase increases viscosity and provides film forming properties that enhance SPF activity on skin.

SUMM

The use of various fragrance-bearing compositions on the **skin** has been known for centuries. However, improving the duration of fragrances on the **skin** has always posed a challenge. In the past, attempts have been made to introduce various materials into fragrance compositions to. . . compositions, and changes in the character of the fragrance have all impaired improvement of the longevity of fragrance on the **skin**. Accordingly, it would be advantageous to prepare a composition capable of imparting fragrance to the **skin** and capable of extending the longevity of the fragrance on the **skin**.

SUMM

chain are capable of extending the longevity of the fragrance to the skin. Accordingly, it is another object of this invention to provide a composition for extending the longevity of fragrance on the skin. It is another object of this invention to provide a method of extending the longevity of fragrance on the skin using such a composition. It is a feature of the composition and method of this invention that the composition contains. . . advantageous in that the use of the polysaccharide alkylether oil soluble polymer extends the longevity of fragrance imparted to the skin by the fragrance composition.

SUMM The delivery of various vitamins to the skin is known to be

beneficial. For example, vitamin C (i.e., ascorbic acid) and vitamin E (i.e., tocopherol) are well known skin care ingredients with proven beneficial free radical scavenger and antioxidant properties. However, to be effective these and other vitamins must be delivered to the skin in the active form. For example, vitamin E is oil soluble, but  ${\bf vitamin}$   ${\bf C}$  is water soluble and is very unstable in water, degrading very rapidly. Thus, effective delivery of vitamin C to the skin in an aqueous system is very difficult to achieve. Accordingly, the use of anhydrous or essentially anhydrous systems to deliver effective amounts of vitamin C to the skin have been attempted. Such systems have employed materials such as petrolatum, waxes, fatty alcohols, fatty acids, polyethylenes and low HLB. . . properties. Thus, it would be advantageous to prepare an anhydrous composition capable of delivering one or more vitamins to the skin which has good stability and cosmetic application properties.

SUMM . . . saturated C.sub.1 -C.sub.24 alkyl chain are capable of delivering the vitamin, including combinations of vitamins C and E, to the skin. Accordingly, it is yet another object of this invention to provide an anhydrous composition for delivering one or more vitamins to the skin. It is another object of this invention to provide a method for delivering one or more vitamins to the skin using such a composition. It is a feature of the composition and method of this invention that the composition contains.

. . use of the polysaccharide alkylether oil soluble polymer provides a stable, cosmetically acceptable vehicle for delivery of vitamins to the skin.

A composition for having enhanced **skin** protection from ultraviolet rays comprises at least one sunscreen composition and at least one polysaccharide alkylether comprising at least two. . . sunscreen composition comprises one or more materials capable of filtering, blocking or absorbing ultraviolet rays. A method for enhancing the **skin** protection properties of sunscreen formulations against ultraviolet rays comprises applying to the **skin** a composition comprising at least one sunscreen composition and at least one polysaccharide alkylether comprising at least two different moieties. .

SUMM A composition for extending the longevity of fragrance on the skin comprises at least one fragrance composition and at least one polysaccharide alkylether comprising at least two different moieties and at. . . composition comprises one or more materials having a fragrant odor. A method for extending the longevity of fragrance on the skin comprises applying to the skin a composition comprising at least one fragrance composition and at least one polysaccharide alkylether comprising at least two different moieties. .

SUMM An anhydrous composition for delivering one or more vitamins to the skin comprises at least one vitamin and at least one polysaccharide alkylether comprising at least two different moieties and at least one hydroxyl group substituted with a saturated C.sub.1 -C.sub.24 alkyl chain. The composition for delivering vitamins to the skin comprises at least one vitamin. For example, the composition may comprise vitamin C, vitamin E, or a combination thereof. A method for delivering one or more vitamins to the skin comprises applying to the skin a composition comprising at least one vitamin and at least one polysaccharide alkylether comprising at least two different moieties and. . .

SUMM All of these compositions are most preferably topically applied to the skin. The polysaccharide alkyl ether has a weight average molecular weight in the range of 1 to 1,000,000, preferably 1 to. . .

DETD The **skin**-protection enhancing composition of this invention comprises at least one sunscreen composition and at least one oil soluble polymer which is. . .

DETD . . . MCX, manufactured by Givaudan, and UVINUL M-40, a benzophenone-3 product manufactured by BASF. The sunscreen composition is employed in the **skin**-protection enhancing composition in a concentration range approved by the United States Food and Drug Administration (FDA). A sunscreen such as. . . OMC is employed in a concentration range of 2 to 7.5 weight percent, based on the total weight of the **skin** protection formulation. Benzophenone-3 is employed in a concentration range of 2 to 6, preferably 2 to 3 weight percent, based on the total weight of the **skin** protection formulation.

DETD . . . Inc. under the AQUALON trade name, most preferably AQUALON AQU-D-3360-L and AQU-3360-H. The polysaccharide alkylether is employed in the enhanced **skin** protection composition in a concentration range of about 0.5 to 10 weight percent, based upon the total weight of the **skin** protection formulation. The invention may be employed in an anhydrous sun protection formulation as well as in oil-in-water or water-in-oil. . .

DETD The following examples illustrate various preferred embodiments of the enhanced **skin** protection composition of this invention. It will be understood that the following examples are illustrative and are not meant to. . .

. . . being bound by any one theory, it is expected that use of the DETD polysaccharide alkylether oil soluble polymer in the skin protection composition of this invention enables the oil-soluble ultraviolet filter or sunscreen material contained in the composition to be distributed more uniformly on the skin topography. It is also expected that the rheological properties are improved and made more flexible with respect to oil phases. . . composition. It is also expected that use of the polysaccharide alkylether prolongs the activity of the sunscreen composition on the skin, and reduces the penetration of oil-soluble sunscreen composition into the skin , thereby lowering the potential of skin irritation due to such penetration. It is also expected that use of the polysaccharide alkylether will enable the level or concentration of the sunscreen or ultraviolet radiation filter material to be reduced in the skin protection composition, thereby reducing the cost and possible harmful side effects of such materials. It is also expected that use of the polysaccharide alkylether will impart improved water-resistant properties to the skin-protection composition, thereby enhancing its use at the beach, pools, while swimming and the like.

DETD . . . polysaccharide alkylether employed in the fragrance extending composition of this invention is as described above with respect to the enhanced **skin** protection composition embodiment of this invention. The absence of any chemical odor in the oil soluble and lipophilic polymer makes. . .

DETD . . . fragrance duration. Formula D prepared in accordance with the invention was found to exhibit significantly longer fragrance duration on the **skin** as compared with control formula E.

DETD . . . Preliminary evaluation tests confirmed that formulation B prepared in accordance with the invention exhibited significantly longer fragrance duration on the **skin**.

DETD . . . alkylether employed in the vitamin delivery composition embodiment of this invention is as described above with respect to the enhanced **skin** protection composition and fragrance-enhancing embodiments of this invention. The oil soluble polymer may be present in the vitamin-delivery composition embodiment. . .

DETD Vitamins which may be employed in this embodiment of the invention include, but not limited to, vitamin A, pro vitamin A, vitamin B.sub.1, vitamin B.sub.2,

vitamin B.sub.3, vitamin B.sub.4,
vitamin B.sub.5, vitamin B.sub.6, vitamin B.sub.12, vitamin
C, vitamin D, vitamin D

.sub.2, vitamin D.sub.3, vitamin E

, vitamin F, vitamin K.sub.l and combinations and derivatives thereof. Preferred vitamins include vitamins C and E, as well as derivatives and combinations thereof. In a particularly preferred embodiment, the invention comprises both  ${\bf vitamin}\ {\bf C}$  and

vitamin E. The vitamins may be present in a concentration from about 0.5-50 percent by weight, preferably 0.5-10 percent by weight, based. . .

DETD

(cps)

DEID _					
Vitamin	n C Suspension				
Phase	Ingredients	s % Wt			
A	Eutanol G	87.40			
A	AQU-D-3360-	-H			
		7.60			
В	Micronized	5.00			
	Ascorbic Ad	cid			
	Total	100.00			
Viscosity	y	83,000			
(cps)					
DETD			_		
Vitamin	n C and E Susper	nsion			
Phase	Ingredients	A Wt. %	B Wt. %		
A	Finsolv TN	64.50	41.00		
A	Tocopherol	1.00	1.00		
A	Wickenol 151		10.00		
A	Cyclomethicone	21.50	35.00		
В	AQU-D-3360-H	8.00	8.00		
C	Vitamin C	5.00	5.00		
	TOTAL	100.00	100.00		
Viscosity					
		99,000	92,000		

- DETD . . . together with a propeller mixer. AQU-D-3360-H was added to the other Phase A ingredients while stirring with a propeller mixture.

  Vitamin C was added to the resulting mixture while stirring with a propeller mixer.
- DETD . . . water absorption properties, the bioavailability of the vitamin or vitamins is enhanced upon application of the vitamin suspension to the **skin**.
- CLM What is claimed is:
  - 1. A composition for extending the longevity of fragrance on the  ${\bf skin}$  comprising at least one fragrance composition and at least one polysaccharide alkylether comprising at least two different moieties and at. . .
  - 12. A method for extending the longevity of fragrance on the **skin** comprising applying to the **skin** a composition comprising at least one fragrance composition and at least one polysaccharide alkylether comprising at least two different moieties.
- L3 ANSWER 12 OF 17 USPATFULL
- PI US 5653970 19970805 <--
- AB The invention relates to personal product compositions containing heteroatom containing alkyl aldonamide compounds and **skin** conditioning agent. Unexpectedly, applicants have found that when these

heteroatom containing alkyl aldonamides are used, benefits such as enhanced stability. . .

SUMM . . . For this reason, a special importance is attached in the cosmetic area to personal products particularly, bath preparations, cleansing preparations, skin care preparations, shaving preparations and deodorant or antiperspirant preparations.

SUMM The primary function of a personal product composition is to cleanse the skin gently without irritation or excessive defatting or overdrying the skin. In addition, successful personal product compositions should not leave the skin tight or taut after frequent routine use. After accomplishing the cleansing action, the personal product composition should leave the skin feeling soft, smooth, silky and moisturized while simultaneously providing a rich copious foam or lather. This has become a difficult. . . in making a totally satisfactory product. For one thing, it is known that certain mild surfactant systems when formulated for skin cleansing, often exhibit poor foam or low lather performance. On the other side, the use of high sudsing surfactants with lather boosters can yield acceptable lather volume, unfortunately however, such surfactant systems are usually harsh to the skin. It will be appreciated that these two factors make the formulation process, a delicate balancing act.

SUMM . . . a personal product composition of the invention, surprisingly provides improved foam, viscosity, clarity and conditioning characteristics while simultaneously making the **skin** feeling soft, smooth, silky and moisturized. These findings are quite unexpected and have not been recognized or appreciated in the. . .

SUMM . . . roll-on, stick, tablet, powdered and bar form. Included among the personal product compositions are bubble bathes, shower gels, body shampoos, skin cleansers or lotions, liquid soaps, toilet bars, syndet bars, sunscreens, shaving creams, deodorants or antiperspirants and the like.

SUMM . . . good shelf life and should not become turbid or produce sedimentation upon standing. Ideal personal product compositions should cleanse the **skin** gently and should not overdry the **skin**. Surprising the personal product compositions of the present invention that comprise a heteroatom containing alkyl aldonamide compound produce clear, stable, . . .

SUMM . . . alkyl carboxybetaines) and mixtures thereof, could result in a clear thickened personal product composition that foams copiously and leaves the **skin** feeling soft, smooth, silky and moisturized.

SUMM U.S. Pat. No. 4,973,473 to Schneider, et al. teaches **skin** treatment compositions in which the primary moisturizing agent may be a gluconamide compound. Methyloxypropyl gluconamide is the only example of. . .

SUMM These compounds are said to be useful as emollients which are substantive to **skin** or hair and are further taught in U.S. Pat. Nos. 3,990,991 to Gerstein, 4,534,964 to Herstein et al. and 4,529,588. . .

SUMM . . . the heteroatom containing alkyl aldonamide compounds of the invention in compositions with for example, certain essential ingredients such as cosurfactants, skin conditioning agents, skin feel mildness agents, suspending agents, hydroxy acids, auxiliary thickening agents and auxiliary agents (see claim 4). There is also clearly. . .

SUMM . . . object of the present invention to provide mild personal product compositions that efficiently remove surface grease and dirt from the skin.

SUMM It is still another object of the present invention to provide new and improved personal product compositions that leave the **skin** feeling fragrant, soft, smooth, silky and moisturized.

SUMM It is a final object of the present invention to provide an improved

method of cleansing and conditioning the **skin**. These and other objects will become readily apparent from the detailed description which follows.

- DETD . . . sought. Such ingredients are well known to those skilled in the art and include, but are not limited to cosurfactants, **skin** conditioning agents, **skin** feel mildness agents, suspending agents, hydroxy acids, auxiliary thickening agents, water and other optional ingredients (auxiliary agents).
- DETD Cationic surfactants have been taught in the art as conditioning agents for the **skin**. Suitable cationic surfactants are broadly exemplified as those of the general formula:
- DETD Skin Conditioning Agents (Moisturizers/Emollients)
- DETD Various materials have been taught in the art for use as agents that condition the **skin**. In general, such conditioning agents are designed to make the **skin** feel soft, smooth, silky and moisturized.
- DETD . . . . term emollient, and is meant to describe a material which imparts a soft, smooth, silky and moisturized feeling to the skin surface.
- One way of moisturizing is to reduce the rate of water loss from the DETD stratum corneum (skin surface) by depositing an occlusive material (emollient or emulsifier) on the skin surface which prevents water evaporation. Mother technique is to add hygroscopic nonocclusive substances (humectants), which will retain water to the stratum corneum, making water available to the skin surface thereby producing the desired cosmetic effect. Nonocclusive moisturizers also function by improving the lubricity of the skin. Both occlusive and nonocclusive moisterizers as well as mixtures thereof are operative in the present invention. Examples of occulusive moisturizers.. . include polyols, fatty acids, certain alkanolamides, pyrrolidone carboxylic acid and their derivatives. It is to be understood that any such skin conditioning agent or mixtures thereof can be employed herein, depending on the formulations desires.
- DETD . . . potassium, ammonium and alkanol ammonium salts of pyrrolidone carboxylic acid, ethyl pyrrolidone carboxylic acid and the like. Typical levels of **skin** conditioning agent are from about 1% to about 40%, preferably from about 2% to about 30%, even more preferably from.
- DETD **Skin** Feel Mildness Agents
- The skin feel mildness agents useful in the present invention include, but are not limited to the cationic, anionic, amphoteric and nonionic polymers used in the cosmetic field. Reduced skin irritation benefits of cationic and nonionic polymers are described in Polymer JR for Skin Care Bulletin, by Union Carbide in (1977). The cationic polymers also provide a desirable soft, smooth and silky feeling to the skin. While wishing not to be bound to theory, it is believed that cationic polymers chemically interact with anionic surfactants to form complexes which may enhance overall mildness to skin characteristics. Also, there is a reason to believe that positively charged cationic polymers can bind with negatively charged sites on the skin to provide a softer skin feel after use. The cationic polymers are most preferred because they provide the best skin feel benefits.
- DETD . . . in the present invention is discribed in U.S. Patent No. 4,438,095 which is incorporated herein by reference. Typical levels of skin conditioning agent are from about 0% to about 5%, preferably from about 0% to about 4%, even more preferably from. . .
- DETD Hydroxy acids have been taught in the art for use as agents that exfoliate dead **skin** cells leaving **skin** smoother and tighter with a more youthful appearance. In addition, hydroxy acid treatments help reduce liver and sun spots as. . .

- DETD . . . and vegetables or by fermentation of corn or sugar substrates) and the like are useful as well. Typical levels of **skin** conditioning agent are from about 0% to about 10%, preferably from about 0% to about 8%, even more preferably from. . .
- DETD Various materials have been taught in the art as agents that are useful in suspending certain performance ingredients such as **skin** feel mildness agents, silicone fluids, and the like, uniformly, thereby assisting in the delivery of the desirable performance attributes associated. . .
- DETD Examples of sunscreens or UV absorbers useful in the present invention which protect the **skin** and certain sensitive ingredients from harmful sunlight include dipropyleneglycol salicylate, octyl salicylate, 2-ethylhexyl p-dimethylaminobenzoate (octyldimethyl-PABA), polyoxyethylene p-dimethylaminobenzoate (PEG-25 PABA), Tri-PABA-panthenol,. . .
- DETD Examples of vitamins useful in the present invention which provide the hair with valuble nutrition include vitamin A (as retinyl acetate, propionate or palmitate) provitamin A (based on carrot extract, as .beta.-carotene), vitamin B.sub.1 (as thiamine mononitrate), vitamin B.sub.2 (as riboflavin), vitamin B. sub.3 (as niacinamide), vitamin B.sub.5 (as pantothenic acid), provitamin B.sub.5 (as panthenol), vitamin B.sub.6 (as pyridoxine hydrochloride, dioctenoate, dilaurate, dipalmitate or tripalmitate), vitamin B.sub.12 (as cyanocobalamin), vitamin B.sub.15 (as pangamic acid), vitamin C (as ascorbic acid), vitamin D.sub.2 (as ergocalciferol), vitamin D.sub.3 (as cholecalciferol), vitamin E (as
  dl-.alpha.-tocopherol acetate, linoleate or nicotinate,), vitamin F (as glyceryl linoleate and glyceryl linolenate), vitamin K.sub.1 (as phytonadione), vitamin K.sub.3. . . bioflavoniod and mixtures thereof. Preferred vitamins are provitamin A, vitamin B.sub.1, vitamin B.sub.2, provitamin B.sub.5, vitamin B.sub.6, vitamin B.sub.12 and vitamin E. Typical levels of vitamin are from about 0% to about 7% by weight of the composition.
- DETD Examples of amino acids useful in the present invention which provide the **skin** with valuble nutrition include alanine, .beta.-alanine, N-methylalanine, N-phenylalanine, .alpha.-aminoisobutyric acid, .alpha.-aminobutyric acid, .alpha.-aminocaproic acid, .epsilon.-aminocaproic acid, glycine, N-ethylglycine, N-propylglycine, N-butylglycine, . .
- DETD Examples of proteins useful in the present invention which provide the skin with valuble nutrition include hydrolyzed casein, hydrolyzed collagen (hydrolyzed animal protein), myristoyl hydrolyzed animal protein, hydrolyzed corn protein, hydrolyzed glycosaminoglycans,.
- DETD . . . present invention which prevent the oxidation of certain ingredients by air and prevent the development of unpleasant, rancid odors include vitamin E (tocopherol), lecithin, wheat germ oil, sodium sulfite, sodium bisulfite, uric acid, propyl gallate, butylated hydroxyanisole (BHA), toluhydroquinone (THQ) sold as.
- DETD . . . adjusted to a pH of about less than 7 to provide a composition that is non-irritating and non-damaging to the **skin** of the consumer. The amount of buffering agent used will be that which is sufficient to provide the desired buffered. . .
- DETD Examples of heeling agents which function to stimulate the growth of healthy skin tissue include allantion, aluminum dihydroxy allantoinate, urea, uric acid, aloe vera gel, methyl manuronate, uronic acids, sucrose octaacetate, menthol, hydrolyzed. . .
- DETD (c) from about 1% to about 40% by weight of the composition is a skin conditioning agent;
- DETD (d) from about 0% to about 5% by weight of the composition is a

```
(c) from about 2% to about 30% by weight of the composition is a
DETD
       skin conditioning agent;
       (d) from about 0% to about 4% by weight of the composition is a
DETD
       skin feel mildness agent;
DETD
       (c) from about 3% to about 25% by weight of the composition is a
       skin conditioning agent;
       (d) from about 0% to about 3% by weight of the composition is a
DETD
       skin feel mildness agent;
       (c) from about 3.1% to about 25% by weight of the composition is a
DETD
       skin conditioning agent;
       (d) from about 0% to about 3% by weight of the composition is a
DETD
       skin feel mildness agent;
            . in a variety of types and forms. A classification according to
DETD
       product type would consist of bath products, cleansing products,
       skin care products, shaving products and
       deodorant/antiperspirant products.
       Examples of skin care products include, but are not limited to
DETD
       hand/body/facial moisturizers, hand/body/facial creams, massage creams,
       hand/body/facial lotions, sunscreen products, tanning products,. . .
       . . . the heteroatom containing alkyl aldonamide compounds of the
DETD
       invention are useful as foam stabilizing agents, thickening agents,
       solubilizing agents and skin conditioning agents. In addition,
       it has been found that the heteroatom containing alkyl aldonamide
       compounds of the invention are also.
                                            . .
DETD
       The present compositions are used in a conventional manner for cleaning
       and/or conditioning the skin. From about 0.1 g to about 15 g
       of a composition is applied to the skin that may or may not be
       thoroughly wetted with water. The composition is worked unto the
       skin from about 30 seconds to about five minutes and then rinsed
       off or left on.
       The zein solubilization assay was developed to determine the biological
DETD
       effects of surfactants on the skin. The protein is normally in
       soluble in water, but can be brought into solution by interaction with
       surfactants. The extent. . . Z. Poly., 233, 848, 1969). The greater
       the zein solubilization, the greater the irritation potential of that
       surfactant on the skin.
       In order to demonstrate the improved ability of heteroatom containing
DETD
      alkyl aldonamide to provide mildness benefits to the skin,
       mixtures of C.sub.8 /C.sub.10 oxypropyl D-gluconamide (C.sub.8 /C.sub.10
       OPG) and sodium lauryl sulfate (SLS) by weight were tested and compared.
         . . so the heteratom containing alkyl aldonamide compounds not anly
DETD
       enhance viscosity and stabilize foam, but are also mild to the
       High Foaming Skin Conditioning Bubble Bath
DETD
       High Foaming Skin Conditioning Bubble Bath Concentrate with
DETD
       Protein
DETD
                3.0
       . . .
32. Hena Extract
                                           0.5
                       0.5
33. Tocopherol --
                                                1.0
   Acetate
    (Vitamin E)
34. Panthenol
    (Vitamin B5)
35. Ethylene Glycol
                            0.6
   Monostearate
36..
                     0.6
31. Panthenol
```

skin feel mildness agent;

```
(Vitamin B5)
32. Tocopheryl
                               2.0
Acetate/Linoleate
(Vitamin E)
33. Butylated
                                          0.1
            0.01
                   0.01
Hydroxytoluene
34. Carboxymethyl
                               1.5
Cellulose
35. Hydroxyethyl
DETD
                2.0
27. Kelp Extract
                                               2.0
            --
28. Tocopheryl Ace-
                                               0.5
tate (Vitamin E)
29. Sodium 5.0
                   5.2
Isethionate
30. Sodium Chloride
                                     0.4
            0.5
                   0.5
                          0.5 0.5
31. Titanium Dioxide
            0.5.
      A Mild Moisturizing Syndet Bar Composition with Vitamin
      E and Bath Oil
DETD
Protein
54. TEA-Coco
                                               18.0
Hydrolyzed Animal
Protein
55. Tocopheryl Ace-
                                               0.3
tate (Vitamin E)
56. Sodium --
                   0.2
                                     0.3
Dehydroacetate
57. Sodium Pyrroli-
                                          4.0
done Carboxylic Acid
58. Disodium.
      An Astringent Facial Cleansing Composition with Protein, Vitamin
DETD
      E and Aloe
DETD
         . . 1.0
38. Isostearic Acid
                                          1.7 --
39. Tocopheryl Ace-
                               0.2
                                          0.1 1.0
tate (Vitamin E)
40. Panthenol
                                               1.0
(Provitamin B5)
41. Retinyl Palmitate
                           3.0
Polypeptide
42. Lecithin
       A Moisturizing Lotion Composition with Antioxidants for Aging
DETD
      A Moisturizing Cream Composition with Alpha Hydroxy Acids and
DETD
```

2.0

```
Vitamin E
DETD
(2%)
46. Carbomer 940
                                         10.0 5.0
(2%)
47. Tocopheryl Ace-
                               0.1
                                    0.2
                                               0.2
tate (Vitamin E)
48. Ascorbic Acid
                                    0.3
(Vitamin C)
49. Ascorbyl Palmitate
                                               0.2
50. Retinyl Palmitate
                                               0.3
(Vitamin A)
51. Bioflavoniod
                                               0.4
52. Ivy Extract
53. Dimethicone
       A Sunscreen Cream Composition with Vitamin E
DETD
DETD
       A Sunscreen Cream Composition with Vitamin E
DETD
35.
    Animal
                                 0.5 0.1
     Collagen
     (Soluble)
    Tocopheryl --
                                      0.1
     Acetate
     (Vitamin E)
    Acetamide --
                                 1.5
     MEA
    Lactamide
                                 1.5
38.
     MEA
39.
    Allantoin --.
       A Nonalcoholic Aftershave Lotion Composition with Vitamin
DETD
       An Aftershave Skin Conditioning Composition
CLM
       What is claimed is:
         ammonium chloride, sodium sulfate, potassium sulfate, magnesium
       sulfate, sodium isethionate, sodium thiosulfate and mixtures thereof;
       (d) about 1% to 40% skin conditioning agent; and (e) water.
     ANSWER 13 OF 17 USPATFULL
PΙ
       US 5641480
                               19970624
SUMM
         . . to cleanse the hair and scalp from soil without stinging or
       irritating the eyes and scalp. Hair soil includes natural skin
       secretions (such as sebum), skin debris, dirt from the
       environment and residue from hair-grooming products applied by the
       consumer. After accomplishing the cleansing action, the.
       U.S. Pat. No. 4,973,473 to Schneider, et al. teaches skin
SUMM
       treatment compositions in which the primary moisturizing agent may be a
       gluconamide compound. Methyloxypropyl gluconamide is the only example
SUMM
       These compounds are said to be useful as emollients which are
       substantive to skin or hair and are further taught in U.S.
       Pat. Nos. 3,990,991 to Gerstein, 4,534,964 to Herstein et al. and
       . . still another object of the present invention to provide mild
SUMM
```

```
skin debris from the hair shaft and scalp.
SUMM
       Examples of vitamins useful in the present invention which provide the
       hair with valuable nutrition include vitamin A (as
       retinyl acetate, propionate or palmitate) provitamin A (based on earrot
       extract, as .beta.-carotene), vitamin B.sub.1 (as thiamine mononitrate),
       vitamin B.sub.2 (as ribofiavin), vitamin B.
       sub.3 (as niacinamide, vitamin B.sub.5 (as pantothenic
       acid), provitamin B.sub.5 (as panthenol), vitamin B.sub.6 (as pyridoxine
       hydrochloride, dioctenoate, dilaurate, dipalmitate or tripalmitate),
       vitamin B.sub.12 (as cyanocobalamin), vitamin B.sub.15 (as pangamic
       acid), vitamin C (as aseorbie add), vitamin
       D.sub.2 (as ergocalciferol), vitamin D.sub.3
       (as cholecalciferol), vitamin E (as
       dl-.alpha.-tocopherol acetate, linoleate or nicotinate,), vitamin F (as
       glyceryl linoleate and glyceryl linolenate), vitamin K.sub.1 (as
       phytonadione), vitamin K.sub.3. . . sterol and mixtures thereof.
       Preferred vitamins are provitamin A, vitamin B.sub.1, vitamin B.sub.2,
       provitamin B.sub.5, vitamin B.sub.6, vitamin B.sub.12 and
       vitamin E. Typical levels of vitamin are from about 0%
       to about 7% by weight of the composition.
SUMM
       . . . present invention which prevent the oxidation of certain
       ingredients by air and prevent the development of unpleasant, rancid
       odors include vitamin E (tocopherol), lecithin,
       wheat germ oil, sodium sulfite, sodium bisulfite, uric acid, propyl
       gallate, butylated hydroxyanisole (BHA), toluhydroquinone (THQ) sold as.
SUMM
            . to a pH of about less than 7 to provide a composition that is
       non-irritating and non-damaging to the hair, skin and eyes of
       the consumer. The mount of buffering agent used will be that which is
       sufficient to provide the.
                                  . .
DETD
       The zein solubilization assay was developed to determine the biological
       effects of surfactants on the skin. The protein is normally in
       soluble in water, but can be brought into solution by interaction with
       surfactants. The extent. . . Z. Poly., 233, 848, 1969). The greater
       the zein solubilization, the greater the irritation potential of that
       surfactant on the skin.
DETD
       In order to demonstrate the improved ability of heteroatom containing
       alkyl aldonamtde to provide mildness benefits to the skin
       (scalp), mixtures of C.sub.8 /C.sub.10 oxypropyl D-gluconamide (C.sub.8
       /C.sub.10 OPG) and sodium lauryl sulfate (SLS) by weight were tested
       and.
DETD
               Protein
                          -- -- -- 1.0
                        -- -- -- O.1
33. Wheat Germ Oil
34. Tocopherol Acetate (Vitamin E)
35. Panthenol (Provitamin B5)
                              -- -- -- 0.5
36. Balsam
    ANSWER 14 OF 17 USPATFULL
L3
                               19970617
PΙ
       US 5639471
                                                                    <--
SUMM
       The NCI also suggests that diets rich in foods containing
       Vitamin C and Vitamin A from
       fruits and vegetables may also reduce the risk of cancer. Epidemiologic
       studies have shown that diets high in Vitamin A and
       Vitamin C are associated with lower risks of some
       kinds of cancers. Therefore, the NCI recommends consumption of a variety
```

hair care compositions that efficiently remove surface grease, dirt and

of fruits and vegetables, including fruit and vegetable juices that are high in Vitamin A and Vitamin C. Especially beneficial are cruciferous vegetables which are good sources of fiber, as well as vitamins and minerals. DRWD . . major sources of dietary fat rather than by eliminating whole categories of foods. For example, by substituting fish, poultry without skin, lean meats and low- or non-fat dairy products for high-fat foods, a patient may lower total fat and SFA intake. TABLE I DRWD Daily Desired Level of Fortification Breakfast Meal Lunch Meal Dinner Meal (308)(35%)Nutrient (35%)VITAMIN A, (IU) 1500 1750 1750 VITAMIN D, (IU) 120 140 140 VITAMIN E, (IU) 10.5 10.5 VITAMIN C, (mg) 30 35 35 VITAMIN B.sub.1, (mg) 0.45 0.53 0.53 VITAMIN B.sub.2, (mg) 0.6 0.51 0.6 VITAMIN B.sub.3, (mg) VITAMIN B.sub.6, (mg) 0.7 0.6 0.7 VITAMIN B.sub.12, (mg) 1.8 2.1 2.1 90 105 BIOTIN, (mcg) 105 FOLIC ACID, (mg) DRWD TABLE III U.S. Recommended Dietary AHowance (USRDA) NUTRIENT USRDA 5000 IU VITAMIN A 1.5 mg VITAMIN B.sub.1 VITAMIN B.sub.2 1.7 mg VITAMIN B.sub.3 20 mg NE.sup.1 2 mg VITAMIN B.sub.6 VITAMIN B.sub.12 6 mcg 60 mg VITAMIN C VITAMIN D 400 IU VITAMIN E 30 IU NONE ESTABLISHED VITAMIN K BIOTIN 300 mcg CALCUIM 1000 mg COPPER 2 mg 400 mcg FOLIC ACID

MANGANESE. . . TABLE IV

150 mcg

18 mg

400 mg

IODINE

MAGNESIUM

IRON

```
DFEA Compositions
                CONCENTRATION
NUTRIENT
                RANGE
                  1125-9900 IU
  VITAMIN A
VITAMIN B.sub.1
                0.41-2.07 \text{ mg}
VITAMIN B.sub.2
                0.23-2.24 mg
  VITAMIN B.sub.3
                6.3-25.3 mg NE
VITAMIN B.sub.6
                0.54-2.75 mg
VITAMIN B.sub.12
                1.08-8.58 \text{ mcg}
  VITAMIN C
                  31.5-330 mg
  VITAMIN D
                  36-682 IU
  VITAMIN E
                  9.45-49.5 IU
VITAMIN K
                0-110 \text{ mcg}
                94.5-412.5 mcg
BIOTIN
                108-1333.2 mg
CALCUIM
                0.95 - 3.63 \text{ mg}
COPPER
                126-660 mcg
FOLIC ACID
                47.25-187.75 mcg
IODINE
IRON
                5.67-20.79 \text{ mg}
MAGNESIUM
                72 - 339.9 \text{ mg}
MANGANESE.
                                            TABLE VIII
Vitamin and Mineral Mixture (Frozen Foods)
              CONCENTRATION
NUTRIENT
                          FORM
                9000 IU
  VITAMIN A
                            Vitamin A
       Palmitate
VITAMIN B.sub.1
              1.88 mg
                          Thiamine Mononitrate
VITAMIN B.sub.2
                          Riboflavin
              2.04 mg
  VITAMIN B.sub.3
              23
                   mg NE Niacinamide
VITAMIN B.sub.6
                          Pyridoxine Hydrochloride
              2.5
                  mg
VITAMIN B.sub.12
                          Vitamin B.sub.12
              7.8 mcg
                300 mg
                            Ascorbic Acid
  VITAMIN C
                            Vitamin D.sub.3
                620
                     ΙU
  VITAMIN D
  VITAMIN E
                45
                     ΙU
                            Vitamin E
       Acetate
VITAMIN K
              100 mcg
                          Vitamin K.sub.1
BIOTIN
              375 mcg
                          Biotin
                          Calcium Citrate/Dicalcium
CALCUIM
              1212 mg
                          Phosphate
              3.3 mg
                          Copper Gluconate
COPPER
```

(250 micron spray dried); 300 mg of Ascorbic Acid; 6.2 mg of

Vitamin D.sub:3 -100 S.D.; 90 mg of Vitamin

E acetate 50% (CWS/F); 10 mg of Vitamin K.sub.1, 1% (spray dried); 1.88 mg of Thiamine Mononitrate; 2.04 mg of Riboflavin;.

TABLE IX

homogenous vitamin mix: 36 mg of Vitamin A Palmitate

. humidity, e.g. in a range of about 35 to 75% RH, to produce a

600.

FOLIC ACID

Vitamin and Mineral Mixture (Cereals)
NUTRIENT CONCENTRATION

FORM

```
VITAMIN A
                 2500 IU
                            Vitamin A
       Palmitate
VITAMIN B.sub.1
               0.59 mg
                          Thiamine Mononitrate
VITAMIN B.sub.2
                          Riboflavin
               0.32 \text{ mg}
 VITAMIN B.sub.3
              7.7
                   mg NE Niacinamide
VITAMIN B.sub.6
               0.84 mg
                          Pyridoxine Hydrochloride
VITAMIN B.sub.12
                          Vitamin B.sub.12
              2.4 mcg
                            Ascorbic Acid/Sodium
 VITAMIN C
                140 mg
                          Ascorbate
                 80
 VITAMIN D
                      ΙU
                            Vitamin D
       .sub.3
 VITAMIN E
                15.75
                    ΙU
                          Vitamin E Acetate
              141.75
BIOTIN
                          Biotin
                   mcq
              123.6
CALCUIM
                          Calcium Carbonate
                    mg
              1.16 mg
                          Copper Gluconate
COPPER
FOLIC ACID
                          Folic Acid
              210 mcg
IODINE
              60.38
                   mcg
                          Potassium.
DETD
                                           TABLE X
```

Vitamin and Mineml Mixture (Soups and Other Retorted Meals)
NUTRIENT CONCENTRANON

FORM

```
9000 IU
                            Vitamin A
  VITAMIN A
       Palmitate
VITAMIN B.sub.1
              2.63 mg
                          Thiamine Mononitrate
VITAMIN B.sub.2
                          Riboflavin
              2.04 mg
  VITAMIN B.sub.3
              23
                   mg NE Niacinamide
VITAMIN B.sub.6
                          Pyridoxine Hydrochloride
              2.5
                  mg
VITAMIN B.sub.12
              7.8 mcg
                          Vitamin B.sub.12
                           Ascorbic Acid
  VITAMIN C
                300 mg
  VITAMIN D
                620
                     ΙU
                            Vitamin D
       .sub.3
                45
                     ΙU
                           Vitamin E
  VITAMIN E
       Acetate
VITAMIN K
              100 mcg
                          Vitamin K.sub.1
              375 mcg
BIOTIN
                          Biotin
CALCUIM
                          Calcium Citrate/Dicalcium
              1212 mg
                          Phosphate
COPPER
              3.3
                          Copper Gluconate
                   mg
FOLIC ACID
              600.
DETD
                     TABLE XI
```

```
Garlic Roll
                     Fortification
                     Level
Nutrient
                       2250
  VITAMIN A,
              (IU)
                       155
  VITAMIN D, (IU)
                       11.25
  VITAMIN E, (IU)
                       75
  VITAMIN C, (mg)
VITAMIN B.sub.1, (mg)
VITAMIN B.sub.2, (mg)
                     0.51
  VITAMIN B. sub. 3,
                    (mg)
VITAMIN B.sub.6, (mg)
VITAMIN B.sub.12, (mg)
                     1.95
BIOTIN, (mcg)
                     93.75
FOLIC ACID, (mg)
PANTOTHENIC ACID, (mg)
                     3.13
VITAMIN K, (mcg)
                     25
CALCIUM, (mg).
                      TABLE XII
DETD
Raisin Bran Cereal
                     Fortification
Nutrient
                     Level
  VITAMIN A, (IU)
                       2500
  VITAMIN D, (IU)
                       80
                       15.75
  VITAMIN E, (IU)
                       140
  VITAMIN C, (mg)
VITAMIN B.sub.1, (mg)
                     0.59
VITAMIN B.sub.2, (mg)
                     0.32
  VITAMIN B.sub.3, (mg)
                     7.7
VITAMIN B.sub.6, (mg)
                     0.84
VITAMIN B.sub.12, (mg)
                     2.4
                     141.75
BIOTIN, (mcg)
FOLIC ACID, (mg)
                     210
PANTOTHENIC ACID, (mg)
                     4.5
CALCIUM, (mg)
                     123.6
COPPER, (mg)
                     1.16
IRON.
DETD
                      TABLE XIII
Apple Crisp
                     Fortification
Nutrient
                     Level
                       1620
  VITAMIN A, (IU)
                       111.6
  VITAMIN D, (IU)
                       8.1
  VITAMIN E, (IU)
  VITAMIN C, (mg)
                       54
```

VITAMIN B.sub.1, (mg)

```
0.34
VITAMIN B.sub.2, (mg)
  VITAMIN B.sub.3, (mg)
                     4.14
VITAMIN B.sub.6, (mg)
VITAMIN B.sub.12, (mg)
BIOTIN, (mcg)
                     67.5
FOLIC ACID, (mg)
                     108
PANTOTHENIC ACID, (mg)
                     2.25
VITAMIN K, (mcg)
                     18
CALCIUM, (mg).
DETD
                      TABLE XIV
Whipped Potatoes
                     Fortification
Nutrient
                     Level
  VITAMIN A, (IU)
                       1080
  VITAMIN D, (IU)
                       74.4
                       5.4
  VITAMIN E, (IU)
                       36
  VITAMIN C, (mg)
VITAMIN B.sub.1, (mg)
                     0.23
VITAMIN B.sub.2, (mg)
  VITAMIN B.sub.3,
                    (mg NE)
                     2.76
VITAMIN B.sub.6, (mg)
                     0.3
VITAMIN B.sub.12, (mcg)
                     0.94
                     45
BIOTIN, (mcg)
                     72
FOLIC ACID, (mcg)
PANTOTHENIC ACID,
                   (mg)
VITAMIN K, (mcg)
CALCIUM, . . .
DETD
                      TABLE XV
Orange Juice Drink
                     Fortification
Nutrient
                     Level
                       1800
  VITAMIN A,
              (IU)
  VITAMIN D,
              (IU)
                       124
  VITAMIN E,
             (IU)
                       9
                       60
  VITAMIN C, (mg)
VITAMIN B.sub.1, (mg)
                     0.38
VITAMIN B.sub.2, (mg)
                     0.41
                    (mg NE)
  VITAMIN B.sub.3,
VITAMIN B.sub.6, (mg)
                     0.5
VITAMIN B.sub.12, (mcg)
                     1.56
                     75
BIOTIN, (mcg)
```

```
FOLIC ACID, (mcg)
PANTOTHENIC ACID, (mg)
                     2.5
VITAMIN K, (mcg)
                     20
CALCIUM, .
DETD
                      TABLE XVI
Vegetable Soup
                     Fortification
Nutrient
                     Level
  VITAMIN A, (IU)
                       2700
  VITAMIN D, (IU)
                       186
  VITAMIN E, (IU)
                       13.5
  VITAMIN C, (mg)
                       90
VITAMIN B.sub.1, (mg)
                     0.79
VITAMIN B.sub.2, (mg)
  VITAMIN B. sub. 3,
                    (mg NE)
                     6.9
VITAMIN B.sub.6, (mg)
                     0.75
VITAMIN B.sub.12, (mcg)
                     2.34
BIOTIN, (mcg)
                     112.1
FOLIC ACID, (mcg)
                     180
PANTOTHENIC ACID,
                  (mg)
                     3.75
VITAMIN K, (mcg)
CALCIUM, . . .
                      TABLE XVII
DETD
Fruit Sauce
                     Fortification
Nutrient
                     Level
                       450
  VITAMIN A,
              (IU)
  VITAMIN D, (IU)
                       31
  VITAMIN E, (IU)
                       2.25
  VITAMIN C, (mg)
                       15
VITAMIN B.sub.1, (mg)
                     0.09
VITAMIN B.sub.2, (mg)
  VITAMIN B. sub. 3, (mg NE)
VITAMIN B.sub.6, (mg)
VITAMIN B.sub.12, (mcg)
                     0.39
                     18.75
BIOTIN, (mcg)
FOLIC ACID, (mcg)
                     30
PANTOTHENIC ACID, (mg)
                     0.63
                     5
VITAMIN K, (mcg)
CALCIUM, . .
DETD
                      TABLE XVIII
Bagel
                     Fortification
Nutrient
                     Level
```

```
VITAMIN A, (IU)
                       450
  VITAMIN D, (IU)
                       31
  VITAMIN E, (IU)
                       2.25
  VITAMIN C, (mg)
                       15
VITAMIN B.sub.1, (mg)
                     0.09
VITAMIN B.sub.2, (mg)
  VITAMIN B.sub.3, (mg NE)
VITAMIN B.sub.6, (mg)
                     0.13
VITAMIN B.sub.12, (mcg)
                     0.39
                     18.75
BIOTIN, (mcg)
FOLIC ACID, (mcg)
                     30
PANTOTHENIC ACID, (mg)
                     0.63
                     60.6
CALCIUM, (mg)
COPPER, (mg).
                      TABLE XIX
DETD
Salisbury Steak
                     Fortification
Nutrient
                     Level
                       2700
  VITAMIN A, (IU)
                       186
  VITAMIN D, (IU)
                       13.5
  VITAMIN E, (IU)
                       90
  VITAMIN C, (mg)
VITAMIN B.sub.1, (mg)
                     0.54
VITAMIN B.sub.2, (mg)
                     0.61
  VITAMIN B.sub.3,
                    (mg NE)
                     6.9
VITAMIN B.sub.6, (mg)
VITAMIN B.sub.12,
                   (mcg)
                     2.34
                     112.1
BIOTIN, (mcg)
FOLIC ACID, (mcg)
                     180
PANTOTHENIC ACID,
                   (mg)
                     3.75
VITAMIN K, (mcg)
                     30
CALCIUM, .
DETD
                      TABLE XX
Salisbury Steak Gravy
                     Fortification
Nutrient
                     Level
                       450
  VITAMIN A, (IU)
                       31
  VITAMIN D, (IU)
                       2.25
  VITAMIN E, (IU)
                       15
  VITAMIN C, (mg)
VITAMIN B.sub.1, (mg)
                     0.09
VITAMIN B.sub.2, (mg)
  VITAMIN B. sub. 3, (mg NE)
```

```
VITAMIN B.sub.6, (mg)
                      0.13
VITAMIN B.sub.12, (mcg)
                      0.39
BIOTIN, (mcg)
                      18.75
FOLIC ACID, (mcg)
                      30
PANTOTHENIC ACID,
                    (mg)
                      0.63
                      5
VITAMIN K, (mcg)
CALCIUM, .
DETD
                                                       Fiber (g)
               7
                       7
                                  7
                                          6
               18
                       33
                                  35
                                          23
Sugar (g)
Protein (g)
               21
                       14
                                  16
                                          13
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
(USRDA)
                  35
                         35
                                     35
                                            35
  Vitamin A
                  55
                         55
                                     55
                                            55
  Vitamin C
               40
                       40
                                  40
                                          40
Calcium
               35
                       35
                                  35
                                          35
Iron
               35
                       35
                                  35
                                          35
Vitamm D
                                            35
                 35
                         35
                                    35
  Vitamin E
                                          35
                                  35
Thiamine
               35
                       35
                       35
                                  35
                                          35
Riboflavin
               35
                                  35
                                          35
Niacin
               35
                       35
Vitamin B.sub.6
               35
                       35
                                  35.
                                                       11
DETD
               19
                       26
                                 20
                                         20
Protein (g)
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
(USRDA)
               SPLIT PEA
                                 TURKEY PASTA
                       CHICKEN
               SOUP
                       NOODLE SOUP
                                 SANDWICH
                                         Meal
                         30
                                    30
                                           30
  Vitamin A
                  30
                 50
                         50
                                   50
                                           50
  Vitamin C
               35
                       35
                                 35
                                         35
Calcium
               30
                       30
                                 30
                                         30
Iron
               30
                       30
                                 30
                                         30
Vitamm D
  Vitamin E
                 30
                         30
                                   30
                                           30
                                 30
Thiamine
               30
                       30
                                         30
Riboflavin
               30
                       30
                                 30
                                         30
               30
                       30
                                 30
                                         30
Niacin
Vitamin B.sub.6
                       30
               30
                                 30.
                                                       24
                                                               31
                                                                         27
                                                                                  33
DETD
PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES
(USRDA)
               GRILLED
                       GRILLED
                               HERB
               BBQ
                       MUSTARD
                                                  POT
                               ROASTED
               CHICKEN
```

CHICKEN

1.15

## CHICKEN MEATLOAF

ROAST

Vitamin A         35         35         35         35         35           Vitamin C         55         55         55         55         55           Calcium         40         40         40         40         40         40           Iron         35         35         35         35         35         35           Vitamin D         35         35         35         35         35         35           Vitamin E         35         35         35         35         35         35           Thiamine         35         35         35         35         35         35           Riboflavin         35         35         35         35         35         35           Niacin         35         35         35         35         35         35						
Calcium       40	Vitamin A	35	35	35	35	35
Iron     35     35     35     35       Vitamin D     35     35     35     35       Vitamin E     35     35     35     35       Thiamine     35     35     35     35       Riboflavin     35     35     35     35       Niacin     35     35     35     35	Vitamin C	55	55	55	55	55
Vitamin D         35         35         35         35         35           Vitamin E         35         35         35         35         35           Thiamine         35         35         35         35         35           Riboflavin         35         35         35         35         35           Niacin         35         35         35         35         35	Calcium	40	40	40	40	40
Vitamin E         35         35         35         35         35           Thiamine         35         35         35         35           Riboflavin         35         35         35         35           Niacin         35         35         35         35	Iron	35	35	35	35	35
Thiamine 35 35 35 35 35 Riboflavin 35 35 35 35 35 Niacin 35 35 35 35 35	Vitamin D	35	35	35	35	35
Riboflavin 35 35 35 35 Niacin 35 35 35 35	Vitamin E	35	. 35	35	35	35
Niacin 35 35 35 35	Thiamine	35	35	35	35	35
	Riboflavin	35	35	35	35	35
	Niacin	35	35	35	35	35
Vitamin 27 28 32 29 25	Vitamin	. 27	28	32	29	25

PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES (USRDA)

SIRLOIN

SALISBURY

BEEF TURKEY TURKEY BEEF

STEAK TIPS TRADITIONAL

GLAZED STEW

Vitamin A	35		35	35		35	35			
Vitamin C	55	!	55	55		55	55			
Calcium	40	40		40		40	40			
Iron	35	35		35	•	35	35			
Vitamin D	35	;	35	35		35	35			
Vitamin E	35	•	35	35		35	35			
Thiamine	35	35		35		35	35			
Riboflavin	35	35		35		35	35			
Niacin	35	35		35		35	35			
Vitamin										
DETD								Fiber	(g)	
	2	1	3		2				_	
Sugar (g)	2	1	9		11					
Protein (g)	6	5	11		10					

PERCENTAGE OF U.S. RECOMMENDED DIETARY ALLOWANCES

4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	4
4	4	4	•
	4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4

. . . life. The trial was also to monitor the safety of the Prepared Diet by monitoring nutritional intake in plasma vitamins (  $Vitamin\ A$  and  $Vitamin\ D$ ) and

mineral (iron), and trace minerals levels.

L3 ANSWER 15 OF 17 USPATFULL

DETD

SUMM

PI US 5422115 19950606

. . . or proposed for the treatment of several other conditions, such as for example alcoholism, various dementias, aggression, schizophrenia, unipolar depression, skin disorders (including contact

dermatitis, atopic dermatitis, seborrhoeic dermatitis, psoriasis and acne), immunological disorders, asthma, multiple sclerosis, rheumatoid arthritis, Crohn's disease,. . .

SUMM . . . soluble) may have difficulty entering primarily lipid environments so presenting problems where such entry (e.g. penetration into cells, into the **skin** or across the blood-brain barrier) is desirable, whereas entry of lithium into such lipid environments will be facilitated for lithium. . .

SUMM . . . may advantageously comprise a dressing with impregnated therein a Li(C.sub.18-22 PUFA) salt. Such dressings may be used for application

to skin lesions with or without occlusion.

SUMM . . . generally be in the form of gels, creams, ointments, sprays, soaps, lotions, shampoo, emulsions or douches, or other cosmetic or skin or hair care formulations, and the compositions may particularly suitably contain as a carrier a further lipophilic component, e.g. a. . . lipid targetting property of the composition. The Li(C.sub.18-22 PUFA) salts are likely to prove particularly valuable for application to the skin because of the rich lipid content of the skin and the need for agents acting on the skin to move easily from lipid to aqueous phases and vice versa. These water soluble Li(C.sub.18-22 PUFA) salts thus enable essential fatty acids to be delivered to the skin in compositions which are particularly cosmetically acceptable and do not feel unduly greasy or oily.

SUMM . . . inactivating lipid-enveloped viruses, such as for example herpetic, pox and wart viruses and other viruses producing pathological effects on the **skin**, and especially sexually transmittable viruses, including viruses transmitting acquired immune deficiency syndrome.

SUMM . . . seborrheic dermatitis mean plasma levels of below 0.025 mM/l are found. Alcoholics, patients with psoriasis, candidiasis, pityriasis and other fungal **skin** infections and sufferers from combination **skin** similarly exhibit depressed lithium plasma levels. Combination **skin** is a troublesome and unsightly complaint manifested by excessive greasiness in certain **skin** areas, such as the forehead and the nose, and excessive dryness in other **skin** areas, such as the sides of the face).

SUMM . . . chemical deficiency, in particular conditions which appear to be associated with immune system malfunction and especially conditions such as combination **skin**, atopic eczema, psoriasis, seborrheic dermatitis, candidiasis, pityriasis, **skin** fungal infections and conditions associated with alcoholism, and the uses and methods of the invention are deemed to relate to. . .

DETD **skin** and Hair Care Compositions

Skin and hair care compositions, such as lotions, creams or shampoos, may be prepared by mixing into a conventional skin or hair care composition sufficient lithium gamma-linolenate and lithium eicosapentaenoate to yield a composition containing 5% lithium gamma-linolenate and 3%. . .

DETD			
Vitamin A	400	0 iU	
Vitamin B.sub.1	1	mg	
Vitamin B.sub.2	1	mg	
Vitamin C	50	mg	
Vitamin D	400	iU	
Calcium carbonate	5	mg	
Lithium eicosapentaenoa	ıte		
	20	mg	
Rolled oats ad	30	g	
DETD			

DETD	
Vitamin A	4000 iU
Vitamin B.sub.1	1.5 mg
Vitamin B.sub.2	1 mg
Vitamin B.sub.6	1 mg

Vitamin B.sub.3	2	mg
Vitamin C	40	mg
Vitamin D	400	iU
Vitamin E	4	mg
Calcium carbonate	5	mg
Lithium gammalinolenate	50	mg
Iron (II) carbonate	10	mg
Manganese sulphate	1	mg
Nicotinamide	15	mg
Tableting base ad .	450.	
CLM What is claimed	is:	

. psychosis, schizophrenia, tardive dyskinesia and depression; disorders associated with smooth muscle spasm; diabetes and complications associated therewith; cancers; alcoholism; combination skin; and cardiovascular disorders, comprising administering to the body an effective amount of a lithium salt of a C.sub.18-22 polyunsaturated fatty. . .

L3 ANSWER 16 OF 17 USPATFULL

SUMM

PI US 5252333 19931012

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SUMM . . . or proposed for the treatment of several other conditions, such as for example alcoholism, various dementias, aggression, schizophrenia, unipolar depression, skin disorders (including contact dermatitis, atopic dermatitis, seborrhoeic dermatitis, psoriasis and acne), immunological disorders, asthma, multiple sclerosis, rheumatoid arthritis, Crohn's disease, . . .

SUMM . . . soluble) may have difficulty entering primarily lipid environments so presenting problems where such entry (e.g. penetration into cells, into the **skin** or across the blood-brain barrier) is desirable, whereas entry of lithium into such lipid environments will be facilitated for lithium. . .

SUMM . . . may advantageously comprise a dressing with impregnated therein a Li(C.sub.18-22 PUFA) salt. Such dressings may be used for application to skin lesions with or without occlusion.

SUMM . . . generally be in the form of gels, creams, ointments, sprays, soaps, lotions, shampoo, emulsions or douches, or other cosmetic or skin or hair care formulations, and the compositions may particularly suitably contain as a carrier a further lipophilic component, e.g. a. . . lipid targetting property of the composition. The Li(C.sub.18-22 PUFA) salts are likely to prove particularly valuable for application to the skin because of the rich lipid content of the skin and the need for agents acting on the skin to move easily from lipid to aqueous phases and vice versa. These water soluble Li(C.sub.18-22 PUFA) salts thus enable essential fatty acids to be delivered to the skin in compositions which are particularly cosmetically acceptable and do not feel unduly greasy or oily.

SUMM . . . inactivating lipid-enveloped viruses, such as for example herpetic, pox and wart viruses and other viruses producing pathological effects on the **skin**, and especially sexually transmittable viruses, including viruses transmitting acquired immune deficiency syndrome.

SUMM . . . seborrheic dermatitis mean plasma levels of below 0.025 mM/1 are found. Alcoholics, patients with psoriasis, candidiasis, pityriasis and other fungal skin infections and sufferers from combination skin similarly exhibit depressed lithium plasma levels. (Combination skin is a troublesome and unsightly complaint manifested by excessive greasiness in certain skin areas, such as the forehead and the nose, and excessive dryness in other skin areas, such as the sides of the face).

. . . chemical deficiency, in particular conditions which appear to be associated with immune system malfunction and especially conditions

dermatitis, candidiasis, pityriasis, skin fungal infections and conditions associated with alcoholism, and the uses and methods of the invention are deemed to relate to. Skin And Hair Care Compositions DETD DETD Skin and hair care compositions, such as lotions, creams or shampoos, may be prepared by mixing into a conventional skin or hair care composition sufficient lithium gamma-linolenate and lithium eicosapentaenoate to yield a composition containing 5% lithium gamma-linolenate and 3%. DETD Vitamin A 4000 iU Vitamin B.sub.1 1 mq Vitamin B.sub.2 1 mg 50 Vitamin C mg 400 Vitamin D iU 5 Calcium carbonate mq Lithium eicosapentaenoate 20 mg Rolled oats ad 30 g DETD 4000 Vitamin A iU Vitamin B.sub.1 1.5 mg Vitamin B.sub.2 1 mg Vitamin B.sub.6 1 mg 2 Vitamin B.sub.3 mg 40 Vitamin C mq 400 iΨ Vitamin D Vitamin E ma Calcium carbonate mq Lithium gammalinolenate 50 mg Iron (II) carbonate 10 mq Manganese sulphate 1 mg Nicotinamide 15 mg Tableting base ad 450. L3 ANSWER 17 OF 17 USPATFULL US 5204134 19930420 . . understood, it is believed that the allergens cause, upon SUMM ingestion or other contact with the body, a specific reagin (or skin sensitizing antibody) to be formed in the bloodstream. The ability to produce reagins, chemically identified as IgE, in response type of symptoms. Allergic reactions range from very mild SUMM symptoms to death. For example, symptoms, both mild and severe, include skin rashes (allergic eczema and urticaria), dermal symptoms, respiratory symptoms (including allergic rhinitis and bronchial asthma), gastrointestinal symptoms, and migraine. Violent. . . based upon one quart of mineral salt solution supplemented with SUMM carbohydrate, hypoallergenic protein and fat: 400 micrograms of water dispersible Vitamin D; 2100 micrograms of water-dispersible Vitamin A; 60 milligrams of Vitamin C acetate; folic acid; calcium pantothenate; biotin; pyridoxine; vitamin B.sub. 3 ; vitamin K.sub.1 (0.1 mg/l); vitamin B.sub.12 (1.5 mg/l); vitamin E (20 .mu.1/1); thiamin (0.60 mg/1); riboflavin (0.6 mg/ml); vitamin B.sub.6 (0.4 mg/ml); minerals such as calcium as phosphate, carbonate or. . .

SUMM . Chloride

63 to 65 mg

such as combination skin, atopic eczema, psoriasis, seborrheic

0.05 to 1.2 mg Iron (fortified) Zinc 0.38 to 0.43 mg Iodine 10 micrograms Amino Acids 10 micrograms Methionine 10 micrograms Cystine Vitamins 210 International Units Vitamin A (water dispersible) ("I.U.") Vitamin C 6.0 mg (as acetate) Vitamin D 42 I.U. (water dispersible) Vitamin E 1.0 mg 0.04 mg Thiamine Riboflavin 0.14 to 0.16 mg Niacin 0°.08 mg Pyridoxine 0.04 to 0.05 mg

0.32 micrograms

5.0 micrograms

Vitamin B.sub.12

Folic Acid